Exhibit D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	
Angela Coleman, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01267	
Mary F. Cone v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00261	DEPOSITION OF ROBERT D. MOORE, D.O.
Teresa Georgilakis, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00829	April 15, 2016
Dawna Hankins v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00369	
Margaret Kirkpatrick v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00746	
Carrie Smith v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00258	

Isabel Swint v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00786)
)

DEPOSITION OF ROBERT D. MOORE, D.O.

April 15, 2016

9:42 a.m.

Suite 1560
3575 Piedmont Road, N.E.
15 Piedmont Center
Atlanta, Georgia

Reported by: F. Renee Finkley, RPR, RMR, CRR, CLR, CCR-B-2289

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EXHIBITS

EXHIBITS

*(Exhibit 6 was retained by counsel for Defendants.)

(Exhibit 1 was marked for identification.)

ROBERT D. MOORE, D.O.,

having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. MAIMBOURG:

Q. Good morning, Doctor. Could you state your name?

A. Robert D. Moore.

Q. And, Dr. Moore, I have marked as Exhibit 1 a copy of the report that was served on us in this case, and I'd like you to take a look at it and identify it as the report you have prepared for this litigation?

A. Yes, it appears to be.

Q. And that your signature on page 42?

A. Yes, it is.

Q. Dated January 21st of 2016?

A. Yes.

Q. Doctor, the purpose of the deposition today is for me to get a full understanding of your opinions as stated in your report. Do you understand that that's why we're here?

A. Yes.

Q. Are you prepared to do that?

A. Yes.

Q. What did you do to prepare for the deposition?

A. Reviewed my report, reviewed pertinent internal documents from Ethicon that I reviewed, depositions, reviewed the literature, as well met with Jim Matthews on two occasions. Once last week for about two hours, once this week for about an hour, and then also just met with Brittany this morning for about a half-hour.

Q. In connection with preparing this report that's marked as Exhibit 1, did you look at the medical records of any plaintiff making claims against Ethicon?

A. Not for this report, no.

Q. So if your report was served in seven cases, and I won't name them, because they're on the notice, would it be fair to say that you have no opinions about any of the alleged injuries of those plaintiffs?

A. Correct.

Q. On your report, specifically on page 42,

where your signature is, you have a list of nine cases where you have given depositions, correct?

A. Yes, and we've given you an updated version of that right there (indicating).

(Exhibit 5 was marked for identification.)

Q. (By Ms. Maimbourg) And I've marked that as Exhibit 5. Is that what you brought today with you?

A. Yes.

Q. I haven't looked at it closely, but the nine cases that are on Exhibit 1, I believe are also on Exhibit 5?

A. Yes, they should be.

Q. In these -- let's just stick to the nine cases that were in your report. Those were cases in which you were designated as an expert witness?

A. Yes. One of them may have been a treating physician. Ms. Teague might have been a treating physician.

Q. As to the other eight, though, you believe you were identified as an expert?

A. Yes.

Q. And in those depositions, did you testify

that the plaintiffs injuries were caused by the various mesh implants that these plaintiffs had?

A. Yes.

Q. Did you testify in any of those cases, the eight cases we're talking about, that the devices implanted were defective in some way?

A. Yes, I believe I did.

Q. Now, in terms of depositions or trial testimony since 2013, which is basically where this list ends, Exhibit 5 would include all of those, right?

A. Yes.

Q. And it looks like since 2014 -- and I apologize, I can't show this to you while I'm looking at it, you've given -- looks like another eight depositions in cases at the request of the Potts Law Firm; does that sound right?

A. Yes mand I don't think -- some of those were combined depositions, so there were -- you know, there may have been two depositions to cover those particular patients. Multiple patients were in like, for example, one deposition.

Q. Would those be in the Mentor cases or the Bard cases?

A. Mentor cases, as well the Bard cases.
Q. What does it mean when you have here 30 Q deposition?
A. So there was a couple patients that the judge deemed that -- I think it was a second wave or a third wave -- that the deposition was going to be by question and answer, written questions and answers. So the questions were just posed, and then I had to answer those questions in a deposition type of a situation.
Q. In a written --
A. It wasn't written, no. They gave us the written questions ahead of time. Then we showed up and we just answered those 30 questions.
Q. Sounds interesting.
MS. MARIGLIANO: That was wave 3 of the Bard cases.
THE WITNESS: Answered the same questions over and over again for each patient. It was --
Q. (By Ms. Maimbourg) So in all of these cases, whether on Exhibit 1 or Exhibit 5, if Bard is named, or Mentor is named, or Boston Scientific is named, in those cases, other than the Teague case,

where you may have just been a treater, you were always testifying as an expert witness?
A. Yes.
Q. Do you know which of them involved a sling product? And feel free to look at 5 and 1.
A. So the Teague was a sling, and then the ones that say Align -- I don't know if the combinations -- so the ones that say just Align on The Potts Law Firm, Crawford, Earles, Laychak, Richard, that was sling product. Bambi Teague was Obtryx; that was a sling. The Boston Scientific both were -- one was -- one was a combo case of a sling and a prolapse, and one was just a sling.
Q. Were any of the products transobturator slings? Is Align a transobturator?
A. No, Align was not.
Q. How about Obtryx?
A. Obtryx is, yes.
Q. So you've testified in at least one case where Obtryx was at issue or more than one?
A. One was a treating physician, and then one, it appears, was a -- was as an expert.
Q. And the name of that case is what?
A. That was Allen versus Boston Scientific.

Q. Any of those other cases involve TOT slings?
A. In the remaining of these cases, I don't know if they had a TOT sling or not at the time of the procedure. The rest of them definitely had prolapse products as well.
Q. Have you ever testified in a case where the plaintiff alleged medical malpractice?
A. As an expert, no. Wait a minute, yes.
Q. How long ago was that?
A. Just a few weeks ago.
Q. Okay. What was the issue in that case?
A. The issue -- I was defending a physician. And the issue was a complication after a TVT sling.
Q. What was the complication?
A. Complication was a large hematoma that occurred after the sling and subsequent pain from that.
Q. And what's the name of that plaintiff?
A. I can get that for you. Let me think one second. Ball versus Kumar.
Q. Kumar is K-U-M-A-R?
A. Yes.
Q. Where is that pending?

A. It was just settled in Florida.
Q. They settled it after your deposition?
A. Yes.
Q. You were testifying on behalf of the physician?
A. Yes.
Q. Was the gist of your opinion that this complication was a known risk?
A. Yes.
Q. And your further opinion was, is that because it was a known risk, and he met the standard of care, there was no liability?
A. Correct. And it was a "she."
Q. Sorry. Gender bias. In terms of your compensation for your medical/legal work, on page 42 of your report, you list what your charges are. Are those accurate?
A. Yes.
Q. So is a three-hour deposition a half day?
A. Yes.
Q. Your report is quite lengthy and detailed. Would you agree with me?
A. Yes.
Q. Did you use a research assistant?

A. No.
Q. How did you put it together?
A. I've written many reports in the previous cases that I've been involved with, so I used those as somewhat of a skeleton framework. And then just went through step by step with reviewing the literature, reviewing internal documents, reviewing depositions, and that sort of thing to ultimately put it together.
Q. How many hours did you spend preparing your general report?
A. I would estimate a couple hundred.
Q. Does that mean 200 or more?
A. 200 or more, yeah.
Q. And you charged for that $1,000 per hour?
A. Yes.
Q. And since my math is really bad, is that -- you've charged at least $200,000 for preparing this report?
A. I haven't charged anything yet. I have not invoiced anything yet, but I will, yes.
Q. When do you plan to invoice it?
A. Probably within the next few weeks.
Q. Do you have an arrangement where you are

paid a contingency?
A. No.
Q. It's a straight hourly arrangement, right?
A. Yes.
Q. And who do you have that arrangement with?
A. Jim Matthews.
Q. Do you have a written contract?
A. No.
Q. So you've been paid nothing as of today's date for the preparation of this report?
A. Correct.
Q. Once you invoice Mr. Matthews, are you willing to provide a copy of your invoice to me?
A. Certainly.
(Exhibit 2 was marked for identification.)
Q. (By Ms. Maimbourg) Doctor, I'm going to hand you Exhibit 2, which is the notice of deposition. Have you seen this before today?
A. Yes.
Q. And you understand that it asks you to bring certain documents, right?
A. Yes.
Q. And it looks like you did bring some

things, so before we started, Brittany handed me a couple of your articles. These were the abstracts and then your publication called the IUGA/ICS classification, et cetera, et cetera. You brought those three --
A. Yes.
Q. -- right? And then you brought two binders, and I don't care whether Brittany or you explain what's in them on the record, but I just want to know on the record what they are.
A. Sure. These are just all of the references, basically, throughout the report.
Q. And they include both internal documents and medical literature?
A. Yes.
Q. If I asked you to find a particular article when we're going through the deposition today, how easy is it going to be for you, because I notice there's not an index?
A. Well, they are -- these are indexed, and I know what's in this, so relatively easily, yes.
Q. I'm not going to do it a lot, but there may be a few that I'm going to ask you to reference?
A. It should just take a minute.

Q. And it looks like you brought a copy of your reliance list, right?
A. Yes.
Q. We're going to mark that. Is there -- and you brought this list of testimony. Is there anything else you brought, other than this thumb drive?
A. No, I don't think so.
MS. MARIGLIANO: He brought a copy of his report, but --
Q. (By Ms. Maimbourg) And the CV?
A. Yes.
MS. MARIGLIANO: And the CV.
MS. MAIMBOURG: Okay. So we're going to mark this thumb drive as Exhibit 6, but I'm only going to do it in a virtual way, and ask you to identify what Exhibit 6 is.
(Exhibit 6 was marked for identification.)
THE WITNESS: There's a thumb drive that has everything that Jim Matthews and the law firm sent to me.
MS. MAIMBOURG: And, Brittany, is it -- can you agree that I may take this with me and

not give it to the court reporter?
MS. MARIGLIANO: Yes, that's fine. Thank you.
Q. (By Ms. Maimbourg) All right. So I'm just going to ask very few question about the notice of deposition. You were asked to bring information about your billing, and we've already talked about that, you haven't invoiced yet, right?
A. Correct.
(Exhibit 3 and Exhibit 4 were marked for identification.)
Q. (By Ms. Maimbourg) In terms of your CV, I'm going to mark -- well, I've marked -- this is the CV, Exhibit 3, that was attached to your report as Exhibit A. And then today, you've brought what I've marked as Exhibit 4. And can you tell me if there's any significant difference between the two of those?
A. I don't think so, but I just wanted to make sure that we had the most recent one. I think I noticed this one was updated December 2015, at least it's noted that, but when I talked to my assistant, she thought she probably had updated it more recently, but didn't change -- or wasn't sure, but didn't change the date, so I said give me the one

that's -- that we have as the most recent.
Q. You do a lot of speaking and publishing, so I assume your CV is updated --
A. Yes.
Q. -- quite often?
A. Yes. So I don't think there's anything different on this one than the one you have, but I just wanted to bring --
Q. Why don't you hand me the two CVs. I'm going to stick them in this stack right here. I may get back to those later. And then in terms of the notice, Number 5 asked you to bring a complete list of the cases in which you testified, and we've already discussed that, right?
A. Yes.
Q. Schedule -- the schedule to this paragraph 16 asks you to bring documents relating any communication involving you and any of the plaintiffs' other experts. Do you have any such documents?
A. I do not.
Q. Have you read any of the general experts' reports that have been proffered at any time in this MDL by plaintiffs against defendants?

A. In the -- this Ethicon MDL?
Q. Yes.
A. I believe I just read one. I think I read Neeraj Kohli's after they were all submitted.
Q. Do you know Dr. Kohli?
A. I do.
Q. Did you say you read it after all the reports were submitted?
A. Yes.
Q. Why is it that you read that one?
A. Because it was a TVT-O document.
Q. Anything in there that you remember or that you agree with or disagree with?
A. I do not -- I don't remember. I don't think there was anything that I didn't agree or disagreed with.
(Exhibit 7 was marked for identification.)
Q. (By Ms. Maimbourg) Doctor, I've marked Exhibit 7, and this is -- was part of your report and this essentially is your reliance list; is that true?
A. Yes.
Q. And how, specifically, was that prepared?
MS. MARIGLIANO: My office prepared this,

the list.
MS. MAIMBOURG: You mean typed it?
MS. MARIGLIANO: Yes.
MS. MAIMBOURG: So -- thank you.
Q. (By Ms. Maimbourg) The F mesh documents, meaning the internal Ethicon documents here, they were provided to you by the plaintiffs' firm, right?
A. Yes.
Q. By Mr. Matthews' firm?
A. Yes.
Q. Did you list here everything that they sent you?
A. I believe so, yes. They listed -- they prepared this and --
MS. MARIGLIANO: I will represent to you that it's my understanding that all of the Ethicon documents that we sent to him are listed in this document.
MS. MAIMBOURG: Okay. Thanks.
Q. (By Ms. Maimbourg) Doctor, do you recognize that by relying on internal documents selected by somebody else, that you may not have a totally objective view of certain things?
MS. MARIGLIANO: Object to the form.

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THE WITNESS: I'm not sure I understand the question.
Q. (By Ms. Maimbourg) Okay. So you did not ask for or obtain access to Ethicon's entire global production, have you?
A. No, I did not.
Q. Have you read every single deposition of every Ethicon employee taken in the MDL? I hope not.
A. No, I don't believe I have.
Q. So to be fair, your review of the Ethicon story, which is contained in the depositions and documents that you were provided, is not a complete story. Would you agree with that?
MS. MARIGLIANO: Object to the form.
THE WITNESS: I would agree that there's documents that I've not seen from either internal documents or depositions, as you've said. So I've relied on -- the only internal documents I've seen, I've relied on the law firm providing me that, yes.
Q. (By Ms. Maimbourg) So you're relying on a law firm representing plaintiffs who claim they are injured to provide you with documents to form your opinions?

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A. Correct, a portion of those.
Q. Right, 'cause right now we're talking about the internal documents, we're not talking about the literature?
A. Correct, or -- yeah, literature, my experience.
Q. Right. So as to the literature, how did literature get on this reliance list? In other words, was literature given to you by Mr. Matthews and then put on the list, or did you give him literature, or was it a combination, or what was it? This is an open-ended question.
A. It was a combination. They gave me some literature, but I also added a lot of literature to that as well.
Q. How long did the process take of putting that literature together? And I guess let me strike that question and ask a different one.
When were you first contacted by Mr. Matthews to be an expert witness on behalf of plaintiffs against Ethicon?
A. I think it was back in either late October or early November of 2014 -- not 2014, I'm sorry, 2015.

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Q. 2015. When did the process start of you reviewing documents, depositions, and medical literature for purposes of writing your report?
A. Right in November.
Q. In terms of putting the literature together, did that process start with Mr. Matthews giving you a list of literature and you adding to it?
A. They initially sent some papers, journal manuscripts, that sort of thing. And then I also, you know, did my own literature review and -- literature review and search and put things together myself as well, yes.
Q. And I assume that with respect to Exhibit 7, it's unlikely you'd be able to say today which of these articles were given to you and which you put on the list?
A. Right. There's a combination of things in there.
Q. In terms of the notice of deposition, which was marked as Exhibit 2, back to that, you have brought your complete file in this case?
A. Yes.
Q. Is there anything you didn't bring?
A. No.

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Q. One of the categories, Number 31, asks for communication between you and counsel for the plaintiff, to the extent that those communications either relate to your compensation, identify facts or data provided to you that you used, and assumptions that you were asked to make. Is there any such correspondence or documentation?
A. No, I don't believe so.
Q. Has all of your communication with Mr. Matthews and others in his firm been on the phone?
A. Yes. And they sent some e-mails for Dropbox files to obtain these files electronically.
MS. MAIMBOURG: Off the record.
(Discussion off the record.)
Q. (By Ms. Maimbourg) All right. From reading your report and looking at your CV, it's my understanding that your current practice is at the Atlanta Center For Laparoscopic Urogynecology and the Beverly Hills Sunset Surgery Center; is that true?
A. Yes.
Q. Does that also go by the name of the International Laparoscopic Center, or words to that effect?

A. We've had kind of several names throughout the years. It also goes under the name, yes, International Urogynecology Associates, as well Miklos & Moore Urogynecology.

Q. Is there some reason for all those names?

A. As we've expanded our practice to a satellite office in Beverly Hills, and now in Dubai, we've just kind of added satellite office names, and then changed the name to International. And then finally figured out we should just call it Miklos & Moore Urogynecology.

Q. I know for the Atlanta Center, you are the director of advanced pelvic surgery or the co-director of urogynecology. How many people or physicians are in the group?

A. There's just my partner, myself as partners. And we have an associate gynecologist that has her own practice. She's a gynecologist, not a urogynecologist.

Q. Does she work at the Atlanta Center For Laparoscopic Urogynecology?

A. She does. She has her own practice there, her own separate business, but she is -- we're involved with that business, so she works with us,

yes.

Q. But she's not your employee?

A. Not -- she's an employee of her own business.

Q. And so when you say you're the co-director of urogynecology at the Atlanta Center, that's you and Dr. Miklos who are the only partners are the co-directors?

A. Yes.

Q. And in terms of the Beverly Hills Sunset Surgery Center, your title there is chief of the division of female pelvic medicine and reconstructive surgery?

A. Yes.

Q. Is that just you and Dr. Miklos there?

A. Currently, yes.

Q. One other thing on your CV or your report that caught my eye was, you list Atlanta Medical Research, Inc., where you are the co-director and managing partner; is that true?

A. Yes.

Q. What is that entity?

A. That's a business that we run out of our practice and office as well here that we do research

trials.

Q. What are you currently doing a research trial on?

A. We've got several trials that we're doing right now. One is a medication to -- it's an FDA trial for medication to treat fibroids, and try to shrink fibroids without going to surgery. Another is an interstitial cystitis medication. Another is an overactive bladder medication. And I think that's the current trials that are being run right now.

Q. Have you --

A. One more. We're also doing a trial with radiofrequency to treat urinary incontinence.

Q. Would that be considered a device?

A. Yes.

Q. Are those clinical trials listed on your CV?

A. They should be. If not, we can get you the --

Q. And how long has Atlanta Medical Research, Inc. been in existence?

A. Since I joined the practice, so at least 2001. Not sure when it was actually started by our partner before that.

Q. Besides that research that you do and your practice, can you identify other significant professional activities that you are involved?

A. Besides just my -- I've got roles in the International Urogynecology Association, as far as being on committees, and a couple different committees. The Laparoscopic Special Interest Group, which takes some work to get involved -- to be ready for the meeting and present and getting some different things ready for training and that sort of thing for the -- that special interest group.

I'm also involved -- I was on the public relations committee as well for the International Urogynecology Association, which again, fair amount of work in getting things together for them. And now I'm on the -- I'm on the board for the Foundation of the International Urogynecology Association, which is a foundation that supports the work that they do in Ghana.

Q. So you practice medicine in maybe three locations?

A. Yes.

Q. That would be Atlanta, Beverly Hills, and Dubai?

A. Dubai is just starting, yes.
Q. And you do research and you're pretty involved with IUGA?
A. Yes, and I've been involved with other organizations throughout the years, but primarily involved with IUGA right now.
Q. How recent is the Dubai part of your business?
A. We just did the grand opening, I think about late last -- no, I think it was earlier this year. And then our first patients are actually going to be this summer?
Q. The summer of 2016?
A. Yes.
Q. What was your motivation to go to Dubai?
A. They requested us to come there. One of our associates from our office out in Los Angeles has been working there for several years. And they did not have a urogynecology division at the hospital where he was working. So he was kind of the one that spearheaded the movement to see -- to get us invited to come there as visiting surgeons.
Q. This is a colleague of yours in Beverly Hills?

A. Yes, David Matlock.
Q. Does he work with you at the surgery center there?
A. No, he owns the surgery center. So I mean, we work with him in that regards, but no, we don't do surgeries with him, we don't share patients with him, per se.
Q. Do you expect that you'll be doing any surgery on women who have had gentle mutilation surgery -- or not -- I guess it's not considered surgery -- genital mutilation?
A. I don't know. There's a possibility of that, yes.
Q. Taking all of these professional activities into account, can you tell me, if you can estimate the percentage involved in patient care including surgery?
A. I would say 80 percent of my time is -- and you want to separate out Atlanta research?
Q. Right, 'cause that's not really patient care, unless you define it as such?
A. Yeah. I mean, it -- to me, it almost is, because we -- you know, these are -- these are typically, you know, patient clinical trials. So we

see patients as part of that. But I mean, if you wanted to say -- I would say 75 percent of my time is patient, clinically oriented.
Q. And what percentage of that is in Atlanta versus Beverly Hills?
A. We're in Beverly Hills for about a week every four to six weeks.
Q. And you actually use the term "we," and I was sort of talking about you. So do you travel with Dr. Miklos?
A. Yes, typically, we cover the Beverly Hills office together, yes.
Q. So when you're in Atlanta, he's in Atlanta. When you're in Beverly Hills, he's in Beverly Hills, unless you're at meetings or something like that?
A. Yes.
Q. How long have you been a partner with him?
A. Since 2001.
Q. In terms of the surgery that you do, if you can tell me what percentage is for treatment of SUI, stress urinary incontinence?
A. Typically, about 80 percent of our patient population is urogynecology in nature, which is

prolapse incontinence. A majority of those patients have incontinence. So I would say 60 to 75 percent of those patients that have prolapse also have incontinence issues that are treated surgically.
Q. So it's a significant part of your practice?
A. Yes.
Q. And you do, I would assume by virtue of your last answer, do treat prolapse in your women patients?
A. Yes.
Q. And you do cosmetic surgery?
A. Yes.
Q. And one of those cosmetic surgeries is labiaplasty?
A. Yes.
Q. How big of a part of your practice is that?
A. The cosmetic side of things, which would include both what we term kind of functional surgery or reconstruction or rejuvenation for sexual function after childbirth trauma, as well as labiaplasty or cosmetic side of things, that's kind of considered both elective and cosmetic. That's about 20 percent

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of the practice. Twenty percent of my surgical practice.

Q. So if someone wants to have their vagina tightened up so that they have better sex, you would -- you consider that cosmetic surgery?

A. Well, I don't consider it cosmetic surgery, but insurance companies consider it cosmetic surgery.

Q. And I know -- how many times have you recreated a hymen?

A. Probably maybe 40.

Q. Is there any medical reason to recreate a hymen?

A. There's social reasons to do that, and it's a patient choice reason to do it. And one would say from their aspect, from the woman's aspect, that there may be a medical need for it to prevent them from being harmed physically for not having an intact hymen.

Q. Who would be harmed physically? Do you mean people who are perhaps of a certain faith?

A. It's not necessarily a faith or religion, it's a cultural issue that women in certain cultures and certain countries, if they don't have an intact

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hymen or bleed per se on their wedding night, that they can be harmed physically, mentally, thrown out of their family, abused in that fashion, so yes.

Q. Are all of the hymens that you've recreated been under those circumstances?

A. I would say 99 percent.

Q. And then the 1 percent actually got on TV, right?

A. Yes.

Q. Has there been more than one hymen that you've created just for sexual pleasure -- or not sexual pleasure, for recreating a honeymoon?

A. There may have been one other woman who was -- she was coming in for reconstruction vaginally. She had been raped by her husband or partner the day she came home from delivering her baby, so she got completely traumatized. And the vagina completely torn open and ripped open and took her many years to kind of get over that.

And then ultimately with her reconstruction, had met a new partner and was getting married and wanted her hymen reconstructed at the time of that procedure to basically give her the control -- these are her words -- give her the

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control and the power back to have the choice of who was going to kind of take that from her per se, so that was the one other one.

Q. Is there any other surgery that you do that takes up any significant part of your time, you know, we've talked about SUI, prolapse, cosmetic. Is there any other category I might have missed?

A. No, I don't believe so.

Q. In terms of surgery to correct or treat stress urinary incontinence, what procedures did you learn in your residency and fellowship? And that would have spanned 1994 through the year 2000?

A. I learned the Burch procedure, pubovaginal sling, midurethral slings, which would have included at that point in time just the retropubic tension-free vaginal tape slings -- the retropubic midurethral slings, including the -- at that point in time, it would have been the TVT, the tension-free vaginal tape sling, as well as injectable agents. Periurethral bulking agents.

Q. Did you learn the MMK?

A. No, at that point in time, it was really kind of going out of vogue, secondary to the -- increased risk of pubic osteomyelitis that was

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occurring after the MMK, so I learned the Burch procedure.

Q. Did you learn it abdominally and laparoscopically?

A. I learned it abdominally in residency and laparoscopically in fellowship, yes.

Q. And you did say you were trained to implant both the pubovaginal sling and the polypropylene midurethral slings?

A. Yes.

Q. Where did you do your fellowship?

A. I did my fellowship at Northside Hospital here in Atlanta.

Q. When you completed your training in 2000 and up through the present, so that would be the last 15 plus years, have you continued to do all of those procedures?

A. I don't -- I haven't done a pubovaginal sling in many years, but all the other procedures, yes.

Q. How frequently do you do a Burch?

A. Now it seems to be mostly our primary procedure to treat stress urinary incontinence. So I do probably two a week.

Q. Do you do them laparoscopically?
A. Yes.
Q. Only?
A. Yes.
Q. And are you still implanting midurethral slings?
A. Yes.
Q. What is the midurethral sling that you currently implant?
A. I've been utilizing the RetroArc, which is the Sparc procedure that's done from below once they release that. And was utilizing the AMS Mini-Arc, Mini sling. Those are no longer available to me, so I will have to take a look and see what products that I will use in the future for midurethral slings.
Q. So just so the record is clear, the Sparc is a midurethral sling, was manufactured by AMS and it's a retropubic?
A. Yes.
Q. And the Mini-Arc is a single incision sling that was manufactured by AMS?
A. Yes.
Q. And your reference to not having those available is a reference to the fact that AMS has

decided to get out of that business?
A. Yes.
Q. Are those off the shelves?
A. They are at our hospital, yes.
Q. Just because you've run out?
A. No, because I think once they called a halt to their business, I think March 31st, the hospital took them off the shelves.
Q. There was not a concern of safety or efficacy of those products when that company decided to stop marketing them, was there?
MS. MARIGLIANO: Object to the form.
THE WITNESS: No, not that I believe.
Q. (By Ms. Maimbourg) And if you had them today, you would be using them?
A. Yes.
Q. At some point in time, you did use the TVT retropubic; is that true?
A. Yes.
Q. When was that?
A. That would have been probably up until about two years ago, when the RetroArc became available.
Q. Why did you make the change?

A. Because I always liked the device sling technology of the Sparc procedure. I wasn't comfortable doing it from above, was more comfortable doing the procedure from below. However, I liked the fact that in their sling and mesh, they had what was called a tensioning suture in place, so that as the plastic sheath was taken off over the mesh, the mesh itself wouldn't stretch out or get what's called a bounce back effect.
So for many years, I was kind of on them to get us a procedure that we could do from below with the Sparc tape to benefit from that tensioning sling.
Q. And when you say below, you mean making an incision in the vagina and then going out the abdomen?
A. Correct.
Q. And the Sparc is -- goes in the abdomen and out the vagina?
A. Correct. It's a -- what would be called a top-down versus a bottom-up approach.
Q. And what is TVT?
A. It's a bottom-up approach.
Q. You did not stop using TVT retropubic

because of any concern about safety or efficacy, did you?
A. I did not. I had to modify the procedure, though, so to eliminate kind of some of the issues I was having with when I was pulling the sheath off, and getting that bounce-back effect that was tensioning the sling too tight right off the bat. So I'd have to modify my technique in order to overcome that issue.
Q. And that issue that you're describing with the sheath technology that -- from -- if I'm understanding your answer, was a concern from tensioning. And therefore, you wouldn't want to tension it too much because then the woman might have retention?
A. Retention, urinary obstructive type symptoms, urgency, frequency, increased risks of basically contracture of the slings and the pore sizes that ultimately can lead to roping and contraction and those sort of phenomenons that we've seen.
Q. We'll hopefully get to all of that.
(Exhibit 8 was marked for identification.)

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Q. (By Ms. Maimbourg) Doctor, I'm handing you Exhibit 8, if you'll just take a look at it. Let me know when you're done.
A. Uh-huh.
Q. All right. This document is a chart, and it's labeled Potential Risks of Non-Mesh SUI Surgery at the top, right?
A. Yes.
Q. And among -- I mean, this would include Burch procedures, pubovaginal sling procedures, and I suppose the MMK, if someone wanted to do an MMK, right?
A. Yes.
Q. Do you agree that this list contains or includes potential risks of non-mesh SUI surgery?
A. Yes.
Q. And if any of these risks actually developed, do you agree the effect on the patient could be temporary or chronic?
MS. MARIGLIANO: Object to the form.
THE WITNESS: Yes.
Q. (By Ms. Maimbourg) And if these risks developed, do you agree that the effect on the patient could be mild, moderate, or severe?

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A. Yes.
Q. In order to do non-mesh SUI surgery, do you believe that doctors should be aware of these risks?
A. Yes.
Q. As to slings, and specifically I think you said in your report that you had implanted -- on page 4, you said you've implanted more than a thousand. You can look at your report if that helps remind you.
A. Yes.
Q. Does this include the period of your residency and fellowship?
A. I mean, that's a small portion of my training, so I didn't implant any mesh slings during my residency. It would have been during my fellowship. So the majority of those were after my training.
Q. And then on page 5, you say, from 2003 to 2008, somewhere in the middle, you say that you used transobturator slings with an outside-in approach, correct?
A. Yes, correct.
Q. And was that the Monarc?
A. Yes.

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Q. And that was manufactured by AMS?
A. Yes.
Q. Were you a preceptor for AMS?
A. Yes.
Q. And that means you were teaching other physicians how to implant?
A. Yes.
Q. Were you acting in any other consultancy capacity with AMS?
A. Yes, I was a consult -- I mean, I was a consultant, I was a speaker for them, I was a preceptor, I did research trials with them.
Q. Did you do any research trials on pelvic mesh devices?
A. Yes.
Q. Which ones?
A. Monarc, Mini-Arc, Apogee, Perigee and Elevate.
Q. Is AMS -- well, let's say, was AMS a competitor of Ethicon for slings and prolapse devices?
A. Yes.
Q. Why did you stop implanting the Monarc?
A. Because I felt the risks outweighed the

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benefit of a transobturator approach and having mesh in the groins, when there were alternatives that were available at that point in time to avoid that.
Q. Is that when you started using the retropubic sling manufactured by AMS, or is that when you went to TVT?
A. No, I had always used the retropubic sling from AMS as a procedure that typically would be used in patients that have failed other procedures, or had severe ISD, which is intrinsic sphincter deficiency or basically a urethra that just doesn't work very well. The retropubic slings had always been shown to be more efficacious in those type of procedures, which was probably overall only about 5 percent of the incontinence patients that I dealt with.
And again, as I stated earlier, AMS didn't have a bottom-up type of an approach with their mesh, and I was not comfortable with, nor felt that we could get as good results from the top-down, therefore, I utilized the TVT sling at that time. I think I also utilized the Caldera sling, which is a little bit stiffer in nature, and I liked the fact that that particular sling, again, did not stretch or become tensioned during the sheath removal.

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Q. And that again was something that impacted efficacy, not safety?
MS. MARIGLIANO: Object to the form.
THE WITNESS: I mean, I would say that it impacted efficacy, but safety in the fact that ultimately safety -- not during the procedure itself, but ultimately, could increase risk of complications later.
Q. (By Ms. Maimbourg) I thought -- my understanding was, is that this tensioning issue had to do with retention or overactive bladder symptoms or things like that after the procedure. Did I misunderstand you?
MS. MARIGLIANO: Object to the form. Go ahead.
THE WITNESS: No, you didn't misunderstand me, but I guess, you know, when we talk about -- if you talk about safety of the procedure during the procedure itself, then, no, I don't think it impacted that.
Q. (By Ms. Maimbourg) I actually wasn't talking about during the procedure, I was talking about -- well, strike it. It's not worth it to go into, given the limited amount of time we have.

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Have you, to this date, ever implanted an Abbrevo?
A. No.
Q. Have you implanted an Exact?
A. Yes.
Q. When?
A. Again, that was the last product I think that was available from kind of the TVT retropubic Align, before I started using the RetroArc.
Q. So if I get -- my understanding is from 2003 to 2008, you used the Monarc sling. You then felt the risks outweighed the benefits, so you stopped doing that, and you went to retropubic slings, either the TVT, the Caldera, or the Exact. And then at some point in time, you went to this AMS product because they developed a bottom-up. Is that true?
A. No.
Q. Okay. What's wrong with that scenario?
A. So throughout that time frame that I was utilizing Monarc, I was also utilizing a retropubic sling for more complex patients, failures, ISD, et cetera, which is probably only about 5 percent of my incontinent population. Monarc was the primary

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procedure during that time frame.
However, during that time frame, I was still also utilizing retropubic slings. Once we had access to the Mini-Arc, at that point in time, that's when I stopped utilizing the Monarc. And then Mini-Arc kind of took over Monarc's place, in the same amount of time frame, the retropubic sling was still being utilized in my hands, 5 to 10 percent of the time.
Q. If a patient came in tomorrow, and you saw her for surgical treatment of SUI, what sling devices would you be able to offer her?
A. I would be able to offer her a retropubic sling approach by any manufacturer that still has one on the market, as well as laparoscopic Burch procedure, or a Mini sling that any company still has on the market.
Q. Are you doing more Burch procedures than slings now?
A. Yes.
Q. And for how long has that been?
A. That has been probably over the last -- it's been slowly occurring over the last two years.

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Q. Have you ever been a consultant for Ethicon?
A. For a very short period of time, right when I was done with fellowship, I think in the time frame of 2001, 2002 time frame.
Q. And you acted at that time as a preceptor for the TVT retropubic?
A. My partner was one of the initial four or five to kind of bring TVT slings to this country, so he was their primary preceptor. I helped him, assisted him, because again, I was young and new to the practice. And then I was involved with a couple labs that I instructed at, cadaver labs for Ethicon. So I wouldn't say -- I was never a primary preceptor that they sent people to. They would send them to my partner.
Q. But if Ethicon's records listed you as being a preceptor at two different cadaver labs, and at an advanced training session, you would have no reason to doubt that, if it was in the 2002 time frame?
A. No, I wouldn't have a reason to doubt it.
(Exhibit 9 was marked for identification.)

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Q. (By Ms. Maimbourg) Doctor, I've handed you what has been marked as Exhibit 9, and it's entitled Potential Risks of Non-Mesh and Mesh SUI Surgeries. Just take a look at it and let me know when you're done.
A. Okay.
Q. So just with respect to the column on the right that's entitled Mesh, do you agree that the right -- that this column lists the risks of mesh surgeries?
MS. MARIGLIANO: Object to the form.
THE WITNESS: Yes, I do.
Q. (By Ms. Maimbourg) And do you agree that any -- if any of these risks develop, that the effect on the patient could be temporary or chronic?
A. Yes.
Q. And do you agree that if any of these risks developed, the effect on the patient could be mild, moderate, or severe?
A. Yes, I do. Relative risks aren't listed certainly here on this chart, so that would be one issue that I'd have with the chart, just listing out complications without putting down actually the relative risks of the different complications.

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Q. Okay. If we have time, we'll go back over that. You know what? Before we move on, I do want to mark three articles that you brought with you today, and I'm just going to have you identify them for the record. What is Exhibit 10, Doctor?
(Exhibit 10 was marked for identification.)
THE WITNESS: This is an abstract that we presented at the American Urogynecology Society meeting in 2014 on Indication of Surgical Treatment of Midurethral Sling Complications, a Multicenter Study.
Q. (By Ms. Maimbourg) Is that -- was that mentioned in your report?
A. Yes.
Q. And then Exhibit 11 is also the same data presented at a different time?
(Exhibit 11 was marked for identification.)
THE WITNESS: No, it's basically just a sub-analysis of the data that this first one that we talked about, Exhibit 10, is just about slings. This one is talking about specifically either slings or pelvic organ prolapse

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indications for removal, and then --
(Exhibit 12 was marked for identification.)
Q. (By Ms. Maimbourg) And then Exhibit 12, you also brought this?
A. Exhibit 12 is kind of the main study that actually classifies every patient that came in with a mesh complication, utilizing the IUGA/ICS classification of synthetic mesh complications of all of these patients. So the first one is just classifying the different complications via the official IUGA/ICS classification system.
Q. When you said the first one, you were actually holding Exhibit 12?
A. Exhibit 12, yes.
Q. Right. So are all of these -- and I apologize, 'cause I didn't have those first two abstracts before today. Is the data in 10 and 11 also in 12? No, is that -- partially?
A. Yes, I would say all of the patients -- it's the same patient population from three centers, our center, Emory University, and Cleveland Clinic, Florida. All the patients, all the mesh complications are the same in each of these papers.

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However, 12, which is really the main paper -- 10 and 11, Exhibit 10 and 11 are sub-analysis of this data.
Q. That helps a lot. Keep those there, because I will ask some questions about 12. Just stick them up there. All right.
(Exhibit 13 was marked for identification.)
Q. (By Ms. Maimbourg) I'm going to mark as Exhibit 13 --
(Discussion off the record.)
Q. (By Ms. Maimbourg) Doctor, this was printed on April 12th of 2016, if you could see that date on the top left of this document. Could you identify what this is?
A. This looks like a page from one of our websites.
Q. And actually, it's the International Center For Laparoscopic Urogynecology, right?
A. Yes.
Q. And that is one of the names of your practice?
A. Yes.
Q. So in this section on TVT sling complications, the first sentence says, Although the

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TVT sling is considered the standard of care, complications can still occur. That's what it says, right?
A. Yes.
Q. And are you referring to any particular type of sling in that sentence that you say TVT?
A. I mean, we're using it more generically as a retropubic midurethral sling.
Q. Would a standard -- strike that.
The second sentence says, It is very important to note that it may not be the mesh itself or the procedure that is the cause of the complication. It may be how the mesh is placed or how the body heals around the mesh that may be part of the underlying cause. That's on the -- your website page today, right?
A. This is actually -- I guess it's still available. I mean, this is an older version of our website, but if you just printed it April 12th, I guess it's still out there and available, so --
Q. Well, is this still your opinion today?
A. Yes, I think we've updated it on our new website as well to say as well, that it certainly depends not only on those factors, but also the

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particular make-up of the mesh itself, meaning, you know, the type of mesh that it is, and certainly that's a factor in addition to these factors right here.
Q. What website would I look to, if I wanted to find that updated information?
A. Miklos & Moore Urogynecology.
Q. Does --
A. And it actually says that right here, too. Of course, the qualities and properties of a particular brand or type of mesh used may also play role in complications.
Q. All right. So what you just mentioned that's on your website, the Miklos & Moore, is also here?
A. Yes.
Q. On this website, the International Center, or on Miklos & Moore, or any of your other websites, do you have any statement cautioning patients against having a sling that is implanted via an obturator approach?
A. Yes.
Q. Where does it say that?
A. It would be underneath the TOT sling

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section of the website.
Q. Which website?
A. Miklos & Moore.
Q. Since I don't have that before me right now, what does it say?
MS. MARIGLIANO: Object to the form. Go ahead.
THE WITNESS: It says while -- and again, I can't quote it. We'd have to take a look at it to quote the exact statement, but the gist of the statement says that -- it describes what a transobturator tape sling is, it describes and states that they still are available on the market today, and surgeons utilize them. However, we, meaning my partner and myself, don't perform the procedures any longer. We don't feel that they should be performed. We feel that the risks outweigh the benefit for the procedure, and that there are safer alternatives that are just as efficacious.
Q. (By Ms. Maimbourg) How long has that statement been on your website?
A. I don't know if it was in this version or not. You'd have to take a look at the TOT sling

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portion of that website, but this -- our new website has been in the makings for at least a year.
Q. In terms of mesh removal, which you describe on page 6 of your report, you have a couple different numbers there, and I just wanted to clarify in my own mind.
MS. MARIGLIANO: I'm sorry, what page?
MS. MAIMBOURG: Six.
Q. (By Ms. Maimbourg) Are you there?
A. Yes.
Q. So if you go down to the bottom, it says, My partner and I have explanted more than 700 mesh devices, with more than 500 since 2010?
A. Uh-huh.
Q. And then up above, on the very first part, you said, More than 500 pieces in the last four years. And since four years would actually be 2011 through 2015, I just wanted to clarify what the accurate numbers are.
A. I would say the accurate numbers are this down here below, because we know -- you know, basically, we've got very good numbers based from the study from the years 2011 to 2013, in which there was 500 pieces of meshes explanted in this trial. We did

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75 percent of those from the three centers, so that was over 300, we've explanted in the last two years. Approximately about a hundred to 120 each year. And so then, prior to 2010, from 2002 through 2010, you know, there was least 200. I don't have those exact numbers.

Q. Of the ones that you've removed, you list here that they've included Gynecare Prolift, Prolift Plus M, Prosima, TVT retropubic, TVT-O, and TVT-Secur slings. I just want to make sure that you are not saying the only mesh devices you've removed are those products; is that true?

A. That is true.

Q. So you've just listed the Ethicon products, but you've also removed products of other manufacturers, true?

A. Yes.

MS. MARIGLIANO: Can we take a break, if you're at a good stopping point?

MS. MAIMBOURG: Sure. Yeah, let's take a break. We've been going about an hour.

(A recess was taken.)

Q. (By Ms. Maimbourg) Doctor, we're back on the record. I've asked you to look at your

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Exhibit 12, which is the data you were referring to, I think, in one of your last answers. So this multi-center study, you already identified the three institutions. You and your partner removed 373 slings, right?

A. Yes.

Q. And that's actually on page 2, you have that data. And in this article, you do not breakdown the type of slings by number, correct?

A. Correct.

Q. And I take that that you removed retropubic single incision TOT inside-out and TOT outside-in?

A. Correct.

Q. Do you have that data somewhere?

A. It's actually in that -- one of those abstracts that we talked about earlier, that's specifically on mesh itself. I believe if you take a break at it, what we've broken down --

Q. Let me ask you this. Does it include a breakdown of how many TOT slings were inside-out versus outside-in in this study?

A. It does not.

Q. Is that data somewhere back at Atlanta

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Research, Inc.?

A. If it's available, yes.

Q. Do you believe it's available?

A. I don't know how many numbers of patients that we actually have identified inside-out versus outside-in.

Q. In this article, you do not draw any conclusions about pain being worse in the patients with TOT inside-out compared to any other sling, do you?

A. No, we do not.

Q. You also do not reach any conclusion to a reasonable degree of certainty as to how the mesh was causing pain, correct?

A. In this particular study?

Q. Yes.

A. No.

Q. In terms of conflict of interest information on the last page, you say, none, right?

A. Correct.

Q. What is the purpose of the conflict of interest provision in medical literature?

A. To provide readers any potential bias that may be involved.

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Q. Did you disclose here that you had testified at least nine times for plaintiffs alleging injuries from pelvic mesh, including slings?

A. No.

Q. Do you believe that a reader of this article is entitled to know that you have been and are continuing to be an expert for the plaintiffs suing mesh manufacturers?

MS. MARIGLIANO: Object to the form.

THE WITNESS: It's not part of the requirements as far as they bring you through a very stringent bias -- or not bias, but disclosure and conflict of interest form. And it's not part of the disclosure process of this journal, or any other journal that I know of right now.

Q. (By Ms. Maimbourg) So you don't believe that it would be important, regardless of the process you went through with this journal, you don't believe it's important for readers of this article to know that you're testifying on behalf of plaintiffs in pelvic mesh litigation involving the very products you are studying?

MS. MARIGLIANO: Object to the form.

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THE WITNESS: I think for this particular article, it's irrelevant. It's just a classification of the numbers of patients that came through that were -- that the types of complications that they had, and the classifications of them.

Q. (By Ms. Maimbourg) You are a member of, I think, 12 different societies -- I looked at your CV -- including ACOG and AUGS; is that true?

A. Yes.

(Exhibit 14 was marked for identification.)

Q. (By Ms. Maimbourg) I'm handing you Exhibit 14. Have you seen this before?

A. No, I have not.

Q. So this is the ACOG and AUGS Practice Bulletin on Urinary Incontinence in Women, dated November 5th, 2015. Did I say that correctly?

A. Yes.

MS. MARIGLIANO: What exhibit number? I'm sorry.

MS. MAIMBOURG: I'm sorry, it's 15 -- no, 14. Did I say it wrong? If I did, I apologize. It's 14.

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Q. (By Ms. Maimbourg) Doctor, on page E 74, I'm going to direct you to a couple statements -- or actually, just probably one. You see the page numbers?

A. Yes.

Q. Over on the right-hand column, it says, There are substantial safety and efficacy data that support the role of synthetic mesh midurethral slings as a primary surgical treatment option for stress urinary incontinence in women. Did I read that correctly?

MS. MARIGLIANO: I don't see where you're at.

MS. MAIMBOURG: Right here (indicating).

Q. (By Ms. Maimbourg) So it's on the right-hand column, last full paragraph.

MS. MARIGLIANO: I'm going to object. You didn't read the sentence in its entirety.

MS. MAIMBOURG: I'm not done. I'm just going one sentence at a time.

MS. MARIGLIANO: I said you didn't read the sentence in its entirety.

Q. (By Ms. Maimbourg) Oh, I'll read the sentence in the entirety. You're not even -- you want to find it, E 74?

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A. Yeah, I'm on E 74.

Q. The paragraph that begins, Although controversy?

A. Okay.

Q. Are you there?

A. Yes.

Q. Okay. I'm going to read it again: Although controversy exists about the role of synthetic mesh used in the vaginal repair of pelvic organ prolapse -- and we're not here talking about pelvic organ prolapse, right?

A. Correct.

Q. There are substantial safety and efficacy data that support the role of synthetic mesh midurethral slings as a primary surgical treatment option for stress urinary incontinence in women. Do you agree with that?

MS. MARIGLIANO: Object to the form. Go ahead.

THE WITNESS: I agree that that's what they state here, and I agree with the statement. However, they don't break it down into which particular slings and midurethral slings they're

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talking about. So for an overall global statement, I think that it needs to specify retropubic Mini slings, and exclude TOT slings, in my opinion.

Q. (By Ms. Maimbourg) The next sentence says, For this reason, and to clarify uncertainty for patients and practitioners, the American Urogynecologic Society and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction published a position statement recognizing polypropylene mesh midurethral slings as the standard of care in the surgical treatment of stress urinary incontinence.

So my question to you first is, are you aware that AUGS and SUFU published a position statement recognizing polypropylene mesh midurethral slings as the standard of care?

A. Yes, as a standard of care.

Q. And do you agree that midurethral slings are considered the standard of care in treating SUI?

MS. MARIGLIANO: Object to the form.

THE WITNESS: No, I don't as a global statement of midurethral slings. I believe, in my opinion, they need to be subclassified into

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each particular type of midurethral sling.
Q. (By Ms. Maimbourg) Have you ever communicated that to AUGS?
A. Not officially, no.
Q. Have you communicated it to ACOG?
A. No.
(Exhibit 15 was marked for identification.)
Q. (By Ms. Maimbourg) I'm going to mark Exhibit 15. Doctor, this is entitled Position Statement on Mesh Midurethral Slings For Stress Urinary Incontinence, and it's an AUGS/SUFU statement, correct?
A. Yes.
Q. And due to the short time here, I'm just going to go to page 3, under the conclusion. Are you there?
A. Yes.
Q. And to give this context, this position statement is talking about all mesh midurethral slings, correct?
A. This, again, gives a global classification of midurethral slings that they are including, yes.
Q. And I understand that you think it should

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probably be broken out, but under the conclusion, does AUGS and SUFU say, last sentence, This procedure, meaning midurethral slings, is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years, and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence. Does it say that?
A. It does say that.
Q. And do you agree with that?
A. Again, I don't agree with the statement as stated, with a global kind of all catch one, midurethral slings, retropubic, TOT, single incision slings. I believe that it needs to be separated out, because I don't believe that the TOT slings have globally improved the lives of women with urinary incontinence. I believe it's caused too many complication, and there are safer alternatives.
Q. And Abbrevo is a safer alternative, right?
MS. MARIGLIANO: Object to the form.
THE WITNESS: Yes.
Q. And Abbrevo is a midurethral sling?
A. It's a type of midurethral sling, yes.
Q. Do you agree with the general proposition

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that midurethral slings have been an important advancement in the treatment of stress urinary incontinence in women?
MS. MARIGLIANO: Object to the form.
THE WITNESS: I believe that some forms of midurethral slings have been an advancement in the treatment of women with urinary incontinence.
(Exhibit 16 was marked for identification.)
Q. (By Ms. Maimbourg) Doctor, I've placed before you Exhibit 16 entitled Frequently Asked Questions By Providers, Midurethral Slings For Stress Urinary Incontinence. And again, this is an AUGS and SUFU document. Have you seen this before?
A. Yes.
Q. And on the bottom of page 1, there's a question, Does the MUS mesh made of polypropylene degrade over time?
I'd like you to read that to yourself, that answer. Do you agree with the answer?
A. I don't agree or disagree. I mean, this is -- we can read it as such as they state this, but I really don't have an opinion on whether or not this

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is true or not.
Q. And this paragraph has to do with the question of whether polypropylene degrades over time, right?
A. Correct.
Q. In terms of your report marked as Exhibit 1, is this the only report you have written in the Ethicon mesh litigation?
A. I've written three case-specific reports as well, patient-specific reports.
Q. Is that with respect to the MDL or outside of the MDL?
A. That's with respect to the MDL.
Q. Did you examine those women?
A. Yes.
Q. Do you know if they are wave 1 cases?
A. I do not.
MS. MARIGLIANO: They are.
Q. (By Ms. Maimbourg) Have you been deposed in those cases?
A. No.
MS. MAIMBOURG: Has that been requested? Do you know?
MS. MARIGLIANO: It's not been requested.

Q. (By Ms. Maimbourg) Do you know the names of any of those patients?
A. I don't -- I don't off the top of my head, no.
Q. Does Exhibit 1 -- would you like to correct anything in your report, before we start looking at it in detail?
A. No, I don't believe so.
Q. I actually have a question to you about it. You are identified as an M.D. on the front page and, in fact, you are not an M.D.; is that true?
A. Oh, I would like to correct that.
Q. You're a D.O.
A. I didn't even notice that.
Q. And when you signed it, though, you were confirming it was accurate, and that these were the opinions that you were going to give at the trial of this -- any of these cases, to a reasonable degree of medical certainty, right?
A. Yes.
Q. On page 8 of your report, you state that you have worked closely with medical device companies in the development and analysis of pelvic repair mesh products. Was that with reference to AMS and what

you already previously described?
A. Yes.
Q. Have you worked with any other company in that way?
A. I did some work early on with Tyco -- U.S. Surgical Tyco with the IBS product, did a little bit of work with Caldera, really mostly as a preceptor. And the work we talked about, small amount of work with Gynecare early on as well with TVT.
Q. In terms of product development, what can you specifically tell me you did?
A. During the different phases of product development with American Medical Systems, looked at different early prototypes, tested early prototypes, gave feedback on improvements, both in incontinence and prolapse procedures.
Q. Is that with respect to the obturator product or retropubic product or both?
A. I was involved with both.
Q. How about the Mini sling for them?
A. Yes.
Q. Did you ever have any involvement in consulting with them as to the content of the

Instructions For Use?
A. Yes, I believe I did, but mostly for a foreign country, which I think was Japan.
Q. What was the unique thing about that? I mean, why would you only do that?
A. They just asked -- because I was involved with -- they wanted the initial Monarc trials. I believe Japan has different regulations that look very closely at the different trials, so they just wanted my input on getting clearance in Japan, and also helping kind of check those, the IFU, and that sort of thing.
Q. Did you ever draft language for any of the IFUs, in terms of adverse reactions or warnings or precautions?
A. No, I don't believe so.
Q. When you were a consultant with AMS, did you draft any professional education materials?
A. No, I had input into some of the different professional education programs, as far as worked with them on presentations and slide presentations and that sort of thing, but they were -- they were the authors, they developed them.
Q. In terms of your opinions, now starting on

page 9, which you have labeled number 1, design defects. The first thing you say in your heading is, Tendency to cause pain, and bladder, bowel, and sexual dysfunction secondary to location of mesh.
What is it about the location of the mesh that creates this tendency? And if you could be brief, I would appreciate it.
MS. MARIGLIANO: Object to the form. Answer as completely as you need to.
THE WITNESS: Well, as briefly as, or as elongated as it may be, specifically, with the transobturator sling or location of the mesh in the periurethral tissues extending out through the obturator muscles, the adductor longus muscles themselves, specifically with the TVT-O having more mesh in the adductor muscles themselves, with that type of placement of the mesh, it's been noted over time that with contraction -- with contraction, ultimately, that can cause pain.
It then causes pelvic floor dysfunction, because of dyssynergia and spasms throughout the muscles that can affect bowel, bladder function, and sexual function throughout the vagina and

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the pelvis.
Q. (By Ms. Maimbourg) So my question was only about the location. So you told me your whole opinion, right?
MS. MARIGLIANO: Object to the form.
THE WITNESS: Yes, but the location of the mesh in the periurethral tissues, as well extending out into specifically with the TOT and TVT-O, obturator internus, externus adductor muscles.
Q. (By Ms. Maimbourg) So in other words, as I understand that, it's where the mesh is lying, and it's the technique of getting it there that you are calling here as a defect?
A. Yes, it's not only where the mesh is lying, but also how it's placed specifically with the TVT-O device, which includes the needles and the mesh itself.
Q. In these two pages, and I'm basically going through this the way you have set it up.
A. Okay.
Q. So in these two pages, subsection A, am I correct that you cite nothing for the proposition that the location of the mesh has a tendency to cause

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pain, bladder, bowel and sexual dysfunction?
MS. MARIGLIANO: You're just saying in subsection A, you're asking if he said that or if he --
MS. MAIMBOURG: Correct.
MS. MARIGLIANO: -- didn't include that?
MS. MAIMBOURG: That's exactly what I'm asking, in these two pages.
MS. MARIGLIANO: I'm just going to object to the form.
THE WITNESS: What I'm describing is the -- in those two pages, and it gets into specifics as far as where the mesh is implanted and how it causes complications at the bottom of page 10, and subset of B. In A itself, it's just describing the placement of the initial TOT, and then the subsequent development of the TVT-O, and how that is placed itself.
Q. (By Ms. Maimbourg) So in these two pages under subsection A, you don't cite any medical literature for the proposition. You cite that in other parts of your report?
A. Yes.
MS. MARIGLIANO: Well --

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Q. (By Ms. Maimbourg) So B --
MS. MARIGLIANO: Object to the form.
Q. (By Ms. Maimbourg) B is entitled, Mesh Implanted in Groin Muscles Causes Complications, and it's essentially one paragraph, right?
A. Yes.
Q. And you say here that the mesh -- bottom of 10 -- these transverse mesh arms damage the levator and obturator and adductor muscles. And so I'm going to stop there, and ask you, what is your support for that statement that the arms damage those muscles?
A. The subsequent papers and literature that have been -- that have described patients that have prolonged groin pain, thigh pain, vaginal pain, dyspareunia from the mesh arms lying within these muscle groups themselves.
Q. Can you identify those articles?
A. Sure. I mean, as far as if we want to take a look at long-term complications, meaning at least pain of any kind of subsequent nature, or having pain, then we can start with some of the initial trials, the de Leval initial trials that basically they relied upon, who's the inventor of the

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product, 26 percent groin pain. They didn't really track that out.
And then as the papers started coming out in the literature, including Laurikainen's original paper, I think was 2007 in the Green Journal of OB/GYN, groin pains of 16 percent at a year, 5 percent persistent groin pain, which is still significantly impacting women at that point in time. And then we can list Yik Lim and Marcus Carey, the same amount -- actually, 24 percent short-term pain, 4 percent long-term pain.
Q. You know what? We'll get into -- are these all cited in your report, 'cause --
A. They are.
Q. -- we'll probably get into some of them.
A. They are.
Q. Do you mind if I move on, and we can talk about them as they come up?
A. Sure.
Q. All right. I wanted to ask you, though, with respect to the definition of prolonged pain, which that's the term you used in your answer, could you tell me your understanding of what that is versus what is postoperative pain? And in your mind, is

there a difference in this analysis?
A. Yes, I mean, I think really any type of postoperative pain should be resolved by six weeks and 12 weeks, probably at the latest. Anything that is beyond that, I believe becomes more of a prolonged pain issue. And certainly something that's going beyond six months to one year is more of a persistent type of pain issue.
Q. So at the top of page 11, you say, If pain results in the levator ani region secondary to the mesh -- what did you mean, secondary to the mesh?
A. Specifically, if there's a mesh arm in that muscle creating contraction, creating fibrosis, a chronic inflammatory reaction, that creates shrinkage of the mesh in the surrounding tissues that creates nerve entrapment or pain for any of those reasons, then that's going to ultimately affect the muscles throughout the pelvic floor.
Q. Now, in this paragraph, same paragraph where we're talking, you do cite the Cochrane review showing -- you say, overall rates of groin pain higher in the TOT group, right?
A. Yes.
Q. You cite the Cochrane review. Now, does

the Cochrane review give a probable explanation or reason for this, or is it just reporting the statistics?
A. The Cochrane review is considered probably the kind of leading authority on data analysis from high level studies, evaluating all of the literature that's been reported.
Q. So is it just reporting the statistics or is it giving a probable explanation?
A. It reports the statistics.
Q. So can you cite to me any article -- and again, we can maybe get into this, but as you sit here right now, in this part of the deposition, can you cite to me any article that has verified, through a scientific process, your previous answer about how the mesh arms in the muscle cause pain through various mechanisms, where that has been proven?
A. I mean, there's many, many articles that describe chronic pain in this region secondary to TVT-O slings, and many come up with scientific reasoning behind it. So I'm not sure really what your -- what your question is, as far as to how you can specifically state the kind of scientific reasoning behind that.

Q. Well, I'll explain to you what I mean. Many of the articles you cite here, which I've read, refer to possibilities. They use the word "may," they use the word "can," and I have not found in any of the articles on your reliance list that you cite, where an author in a scientific publication has said, to a reasonable degree of medical probability, or similar words, that the mesh arms in the muscles are causing the type of contraction and scarring that you believe, in your opinion, causes the pain. Have I missed something, is there an article that does that?
MS. MARIGLIANO: Object to the form.
THE WITNESS: Well, I think that basically journal articles, and journals themselves, the verbiage that is required is different. That is what that particular author is stating. They also would state that if the mesh wasn't there, certainly the patient wouldn't have pain in that specific location.
So there's been multiple studies that have looked at anatomical directions of this mesh, where it's going, the TVT-O in relationship to the obturator nerves. Also saying why are these patients in the TVT-Os having more groin pain

than those that don't have mesh in that specific area.
And so although they may say "may" or "perhaps" or "theoretically," which is verbiage that journals, medical journals require, it's in my opinion, to a medical degree of certainty, that this is what's causing these complications.
Q. (By Ms. Maimbourg) And what is your personal opinion based on?
A. My personal opinion is based on the -- my medical training, my experience, my taking care of patients with these type of complications, implanting and doing research trials on every type of avenue that you can with midurethral slings. And knowing that we don't see groin pain in patients that have a retropubic sling that is similar to this type of a pain, when the mesh is in the muscle or irritating the nerve directly.
Q. Doctor, on page 12 of your report, when we're talking about pain syndromes, one of the articles you cite several times in your report is Teo. Did I say that right? Is it -- it's T-E-O?
A. Correct. I'm not sure of the pronunciation.

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Q. I was wondering if we could go off the record for a minute, so you could locate that in your binder?

MS. MARIGLIANO: We can -- it's -- oh, it's in there.

THE WITNESS: No, it's right here.

MS. MAIMBOURG: I don't how long it's going to take.

(Discussion off the record.)

Q. (By Ms. Maimbourg) What is the publication date on the bottom, to the right?

A. 2011.

Q. No, the month?

A. April.

Q. All right, so -- 'cause you have February cited here, and I wanted to make sure that I have the same article. Let me see yours, just to make sure it's the same as mine. Yes, it is. Okay. Doctor, I'm actually going to mark my copy, so you can put yours back in your notebook?

(Exhibit 17 was marked for identification.)

Q. (By Ms. Maimbourg) And you describe on page 12 of your report that this trial by Teo -- do

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you think that's how he pronounces it? T-E-O? How would you pronounce that? You don't know?

A. I would have say Teo.

Q. Teo. All right. So you say in your report on page 12, This trial -- I believe you're talking about this trial, Teo -- was perhaps the clearest example of the clinical and scientific impact of pain syndromes caused by the TVT-O, and comes from the results of an independent study that was performed by several of Ethicon's KOLs. So that's what you're referring to, Teo, right?

A. Yes.

Q. Now, you say in your report that the investigators stopped the trial, because of excess pain reports in the TVT-O arm, and you put in parentheses, 26.4 percent pain reported at six months, right?

A. Yes.

Q. And I think you actually referred to that in one of your previous answers. So I'd like you to go to page 1351 of the article, under the section that's entitled, Results. Are you there? Results, 1351?

A. Yes.

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Q. The second paragraph that says, during recruitment? Are you there?

A. Uh-huh.

Q. This paragraph says, During recruitment, a few studies were published showing similar cure rates for the two procedures, meaning obturator and retropubic, but a high incidence of leg pain in patients after receiving a transobturator tape. After discussing these data at an investigator meeting, we decided to stop recruitment before the full calculated sample was recruited, since it was deemed that clinical equipoise had been lost?

A. Correct.

Q. So the study was not stopped, as you state, because of excess pain reports in the TVT-O arm; is that true?

A. I believe it was due to the pain that they were seeing as well as the discussion they had based on that, and the literature that was in the -- that had been being published.

Q. Well, in fact, that's not what that paragraph says under Results, does it?

A. No, but I believe in the discussion, they talk about that as well.

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Q. And then you say in your report that the authors concluded it was no longer ethical to use the TVT-O device, given the clear negative impact on patient health. And if you look at the Results section, where we just were a minute ago -- you're there, you're on the right page.

A. Okay.

Q. It says, We believed it was no longer ethical to randomize women to the TVT-O arm, in light of these published studies --

A. Correct.

Q. -- but data on women already recruited would be of value, right? Those two sentences are different, are they not?

A. They're saying that those -- that it would still be of value, that they were already -- that those patients were already implanted and certainly -- but they're not going to implant anymore, they're not going to recruit anymore. So I don't know whether or not these patients had already been implanted or not.

Q. I guess it would be an unfair reading of your report for anyone to believe that you were saying here that the authors of this article believed

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it was unethical to use the TVT-O device, that would be an unfair reading of your statement.

MS. MARIGLIANO: Object to the form.

Q. (By Ms. Maimbourg) Right?

A. I think that what the authors are saying is that they believe that it's unethical to implant and/or recruit any more patients to continue this patient trial, and implant anymore TVT-Os. And that based on their review of the literature and their initial findings of a very high amount of groin pain in those patients.

Q. All right. In the conclusion of the article, on page 1355, the authors state, Short-term cure rates at six months are similar for the two procedures. TVT-O results in a higher level of postoperative and leg pain, although these problems are transient. And then it says, The two procedures have a high cure rate with a low rate of complications, right? Right?

A. Yes, that's what it states.

Q. All right. So you, in your report, several times quote a concluding message that I cannot find in this article. And that concluding message says, in your report, page 12, Given the

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comparable efficacy of the procedures, it seems preferable to recommend retropubic tape placement to avoid a high incidence of leg pain. Can you tell me where in the article it says that?

MS. MARIGLIANO: I'm going to object. He's not saying he's quoting that.

Q. (By Ms. Maimbourg) Well, can you tell me, even if you're not quoting it, can you tell me where in the article, the authors state, it seems preferable to recommend retropubic tape placement, or is that your conclusion, your own concluding message?

A. I mean, I'd have to go through this, you know, kind of line by line to take a look at the -- the last paragraph -- to take a look at, you know, their exact verbiage throughout the thing. I don't know if I'm quoting them, if you're saying you don't see those exact words throughout there, I'll take your word on that. But if -- that was my conclusion as well as their summaries of their discussion and their results.

Q. (By Ms. Maimbourg) So if you quote something usually in your report, you would have it as a single-spaced indented quote, right?

MS. MARIGLIANO: Object to the form.

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THE WITNESS: It may be, or it's in quotations.

Q. (By Ms. Maimbourg) Well, take a look at page 40 of your report, where you also quote this article by Teo, the concluding message?

A. Okay.

Q. Are you on page 40 looking at it?

A. Uh-huh.

Q. Does that look like a quote to you? The way it's set off, single-spaced indented?

A. Again, I don't know specifically if this paragraph was supposed to be a quote directly from the article.

Q. In terms of the leg pain, you say here, this -- we're on page 13 in your report, This article was not the first to show that TVT-O caused leg, groin, thigh pain in more than one in four women who were implanted, right?

A. Yes.

Q. And this study that we've been talking about, the Teo study, involved 127 women. And, in fact, if you look at the page 1354, they do say that leg pain was experienced by 26.4 percent of women in the TVT-O group, right?

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A. Yes.

Q. And the article also says, The problem resolves spontaneously within three months, right?

A. Correct.

Q. And that would be within the postoperative period that you previously defined?

A. Yes, in their particular study.

Q. So this study, in particular, does not support your statement, or your claim that this leg and groin pain can be severe, chronic, life-long, and debilitating, does it?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Not the particular study, but if you continue on in the discussion, they do have verbiage that does talk about those concerns. And actually, a couple of the papers we just talked about, including Laurikainen, as well as Yik Lim, as well as the Latthe meta analysis as well.

Q. (By Ms. Maimbourg) This study does not give any support for your claim that it's the proximity of the sling to nerves that is responsible for causing the pain, does it?

MS. MARIGLIANO: Object to the form.

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THE WITNESS: This study basically shows that when you place mesh tape into the groin muscles, it can cause a significant amount of albeit postoperative pain in this particular patient population, but also lead to longer periods of pain that's been shown in other studies.

Q. (By Ms. Maimbourg) The purpose of this study was not to prove that, and it doesn't show it, right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Well, the purpose of this study may have been to prove it, and take a look, but they stopped the study, and didn't look at patients beyond six months.

Q. (By Ms. Maimbourg) I'm not talking -- my last question, I apologize if it was not clear, but I really wasn't talking about longevity. I was talking about mechanism.

A. Okay.

Q. And, you know, the authors of this article talk about possibilities, and they don't talk about -- they don't give an opinion in this article, and they don't prove an opinion as to what is causing

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this postoperative pain, is that true?

MS. MARIGLIANO: Object to the form.

Q. (By Ms. Maimbourg) The only statements are on page -- at the top of 1355, talk -- talks in terms of possibilities?

A. Yeah, and they -- but they do go on to say that cadaveric studies have revealed that the tape passes much closer to the obturator nerve using the inside-out than the outside technique. This could possibly cause the obturator nerve to be more susceptible to damage, inflammation and edema, resulting in pain. Neuropathy resulting in gait abnormality and numbness has also been reported, and seems to be associated more with the inside-out technique.

So I think they are giving their opinions as to what the cause of pain is in this TVT-O procedure.

Q. So they're talking about possibilities here, correct? That's the word they use?

A. They are certainly talking about possibilities and utilizing their expertise in being researchers, clinicians, experts in urogynecology to say what is the potential cause of this pain.

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Q. So researcher -- researchers are fundamentally scientists, right?

A. Yes.

Q. And they deal in possibilities and probabilities?

A. They do. And when they're writing for --

Q. I didn't have a question.

A. Okay.

Q. And, in fact, in your report, you say your opinions you hold to a reasonable degree of medical certainty, I think you used the term, right?

A. Yes.

Q. And you're not giving opinions to possibilities, right?

A. I'm giving opinions, based on a reasonable degree of medical certainty, which in this instance, we're taking a look at risk versus benefits, and risks outweighing benefits with the TVT-O procedure. And some of these journals hold a higher degree of probability and require that to be able to say certain verbiage. So this is why investigators will say these types of -- utilize this type of language in their studies.

Q. So maybe if these authors had put in the

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word probable, their article may not have been accepted, because it would not have passed the peer-review process, because it's bad science, right?

MS. MARIGLIANO: I'm going to object to the form. You're confusing legal verbiage with verbiage that's using medical in articles.

MS. MAIMBOURG: You're not allowed to make speaking objections, I'm sorry.

MS. MARIGLIANO: So that's my objection.

THE WITNESS: Well, we don't know that.

Q. (By Ms. Maimbourg) We don't know that. We would be speculating, right?

A. Yes.

Q. So let's move on to page 13 through 24 of your report, which is the next section, quite long. And it's entitled, Inside-Out Technique of TVT-O Increases Risk of Nerve Injury/Pain. So when I look at this section, particularly page 14, and I'm looking kind of down here at the bottom, I think what you're saying here is that the technique of inserting the TVT-O puts it too close to certain nerves, which could actually damage the nerve at implantation or be close enough, so that fibrosis around the mesh could very easily cause nerve damage and pain. Does that

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sort of summarize what you're saying about this inside-out technique?

MS. MARIGLIANO: I'm just going to object to the form.

THE WITNESS: It's -- yes, it's talking about one aspect of the -- of the pain.

Q. (By Ms. Maimbourg) And this defect has to do with the technique of implanting the product. And in this particular part of your opinion, you're not talking about the product itself, you're talking about the technique of implanting?

A. Well, I'm talking about the product, because the product involves the implantation process of going from the inside-out. It's part of the product, it's part of the device as all -- all of the different components of it are.

Q. So you're defining the technique as the same as the product?

A. The technique is part of the product. This particular product was the only one that was developed to go from inside to outside. And specifically, the way that it's placed, including all of the components of the product, including the metal wing tip guide, the needles, the mesh, the sheath are

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all part of the procedure.

Q. Right, but you're -- the title of this section of your report is, The Technique of TVT-O Increases Risk of Nerve Injury/Pain, right? That's how you titled it?

A. Correct.

Q. All right. And in part of this section, you quote an article by Piet Hinoul, and I believe you say on page 15 -- well, take a look at what you say there. Are you there in the report?

A. Yes.

MS. MARIGLIANO: I'm not there. Oh, you're talking about on page 15, okay, I see.

Q. (By Ms. Maimbourg) So you quote him to -- that he states that, The suspicion that the inside-out procedure is linked to more neurological injuries was already raised in de Leval's original article. A recent review of the data collected by the MAUDE database also implies more pain, et cetera, et cetera, right?

A. Yes.

(Exhibit 18 was marked for identification.)

Q. (By Ms. Maimbourg) I'm handing you that

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article that you've quoted, and I'd like you to go to page 1205, so we can read the rest of the quote. Could you go to page 1205, I'm sorry.

A. 1205 is the first page.

MS. MARIGLIANO: Look up here (indicating).

THE WITNESS: Okay. Got it. Okay.

Q. (By Ms. Maimbourg) The column on the left, I'm going to show you mine. See this green, that's where you quoted?

A. Okay.

Q. Okay. And I'm going go to after that quote. After the quote about the MAUDE database, Dr. Hinoul says that the MAUDE database needs to be interpreted cautiously, as no incidence rate can be derived from them, and reporting bias cannot be accounted for.

Do you agree with that, with respect to the MAUDE database?

A. I would agree that incident rate cannot be derived from them, and reporting bias also cannot be accounted for.

Q. And then he goes on to cite an article by Debodinance that was a non-randomized prospective

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study compared outside-in Monarc to inside-out TVT-O, and found no difference in thigh pain between both groups, right?

A. He did.

Q. And that -- and that article would be contrary to your opinions in this case that the inside-out approach causes an increase of pain over the outside-in, right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Not necessarily. I mean, there's one study that he quotes, and there's probably a couple more that show the same amount of groin pain in the inside-out versus the outside-in. However, there's multiple -- more studies that also show an increased amount of pain with the inside-out versus the outside-in.

So he's quoting one particular study and there may be a couple more, but I can probably quote more studies overall that show a higher rate of pain with inside-out TVT-O versus outside-in approach.

Q. (By Ms. Maimbourg) You did not choose to put the Debodinance article in your report, because it doesn't support your opinions, right?

MS. MARIGLIANO: Object to the form.
THE WITNESS: The Debodinance article is part of the list of papers that's in my -- that's in -- that's in my reliance list.
Q. (By Ms. Maimbourg) Was that one that you put there, or did the plaintiffs give it to you?
A. The Debodinance? I don't know.
Q. You also talk about the Haddad article on page 15 and 16?
A. Yes.
Q. You have a lot of quotes from there. I'll pull it out and mark it, but -- if you want. It seems to me that all the quotes that you have here are merely the author's regurgitation of certain articles, and do not scientifically establish the truth of anything they're saying.
MS. MARIGLIANO: Object to the form.
THE WITNESS: Well, I wouldn't say -- again, I mean, we're getting into these discussions about what's science and what's truth, and what's a reasonable degree of certainty. That's the verbiage that's used in literature and journals versus the degree of certainty of what they -- they might have

opinions on. What they're doing here is showing all of the different literature supporting their findings and their views as well, and discussing these issues and complications.
Q. (By Ms. Maimbourg) Doctor, that article had to do with BMI, and it didn't even reach statistical significance, right?
A. I don't know that per se, as far as the statistical significance.
Q. And all of these statements actually had nothing to do with their -- the purpose of their study, they were just giving background right?
MS. MARIGLIANO: Object to the form.
THE WITNESS: Again, correct, they were talking about -- you said they were just regurgitating other papers, but not saying anything scientifically. I think that they're supporting -- when one writes a discussion to a paper, they're supporting either their theories or other theories with different papers in the literature.
Q. (By Ms. Maimbourg) So on the next page, when you talk about -- well, we're on 16 and 17. I didn't mean it skip too far ahead. You cite two

articles, Collinet and Lim, L-I-M, in support of your statement that a number of studies have suggested a high-risk of postoperative groin pain with the inside-out treatment.
When you use the term, postoperative groin pain here, are you referring to that six to 12-week period after implant?
A. I am here, but these particular papers also are ones that show a higher rate of long-term groin pain up to a year.
Q. So the Collinet paper only went through 12 weeks, right?
A. No, the Collinet paper is the French registry of, I think, 985 patients that reported on one-year pain rates of 3 percent. Actually, this is wrong, it's 4.7. That should be 2.7, which I think --
Q. It should be 2.7, right?
A. It's 2.7 percent, right. Yeah, and that's quoted later, so that's a typo there.
Q. And when you're saying there, what page are you referring to?
A. Page 17, about halfway down, residual rate of pain of 2.7 percent.

(Exhibit 19 was marked for identification.)
Q. (By Ms. Maimbourg) So if we look at the Collinet article, which I've placed before you as Exhibit 19, this study did not look at long-term pain, as far as I know, because if you look on page 713, they're talking about four to 12 weeks. Maybe I missed something, but this does not appear to be a long-term pain article.
A. Residual pain of 2.7 percent.
Q. It says, up above, postoperative complications occurring immediately after surgery, or by the first follow-up visit, four to 12 weeks, are shown in table 3. And table 3, residual pain, 2.7 percent. So the Collinet article is not about long-term pain.
A. Right, they quote residual pain at 12 weeks, yes.
Q. On page 18, of your report -- are you there?
A. Yes.
Q. Right about here (indicating), Ethicon should never have released an inside-out technique?
A. Okay.

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Q. Do you see that? That that's your opinion, right?
A. Yes.
Q. And this is what we've been talking about here, they should never have released a -- this technique, right?
A. The inside-out technique is the TVT-O, so that's what I'm referring to.
Q. Now, you cite to Doctor -- or Professor de Leval's supposed statements on page 18. And just to be clear, you're citing an internal report, where someone is reporting what Dr. de Leval said, right?
A. Yes.
Q. Is that what it appears to be?
A. Yes.
Q. And you have this in single-spaced paragraph indented, which would imply it's a quote. Did you mean to imply it was a quote?
A. Yes.
Q. And do you practice evidence-based medicine in your job as a urogynecologist and surgeon?
A. Yes, I try to.
Q. Do you consider internal company documents

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and e-mails to be a part of evidence-based machine?
A. I think that it's a part of good medicine to know all the information that you can know, so it may ultimately become part of evidence-base medicine.
Q. You've implanted devices, other than pelvic mesh?
A. Yes.
Q. Can you give me an example?
A. The InterStim device.
Q. Okay, that's a good one. Let's talk about InterStim. Either before implanting your first one, or at any time in your practice, have you ever asked the manufacturer the InterStim to give you their internal memos and e-mails regarding the development of the product?
A. No, but we expect the representatives of that company to be forthright and forthcoming with any and all information that they may have about their product, pluses or minuses, negatives or positives.
Q. When you were a consultant to AMS regarding Monarc, did you ever tell the people you were working with that they should distribute their internal company e-mails and their internal

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memorandums to sales reps and to doctors, did you ever tell them to do that?
A. I think they did distribute a lot to sales reps, probably not to doctors. And I think I would tell them, and did tell them that anything that they had in their internal documents that pertained to patient safety or information that doctors could utilize or needed to utilize, that they should be forthright and forthcoming with all of that information.
Q. Is there anything you, in particular, remember that -- content-wise, that you thought they should have taken from their internal e-mails and distributed to doctors?
A. No, not specifically.
MS. MARIGLIANO: When you get to a decent stopping point -- I can wait a little while, just want to give a heads up.
MS. MAIMBOURG: We'll finish one more section.
Q. (By Ms. Maimbourg) On page 18 and 19, I'm going to ask you various questions about these statements here, and ask what the support is for them, okay?

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A. Okay.
Q. So you say, As the suburethral portion and the arms of the TVT-O mesh scar in, the tissues surrounding the mesh contract or shrink, which can entrap nerves, deform the vagina and pelvic anatomy, and cause severe chronic pain as the chronic inflammation and foreign body reaction to the mesh continues.
And you have a footnote 2 -- end note, I guess I'd call that. Is all of -- everything that you believe supports that statement, is that in that footnote?
MS. MARIGLIANO: Object to the form.
Q. (By Ms. Maimbourg) Or do you want to add anything?
A. No, I mean, I think that you also have to add the breadth of literature that's done primarily on mesh contraction, scar plating, foreign body reaction, fibrosis, nerve entrapment, the works of Cobb, Kling , Klosterhalfen, and all of that body of work. That's a portion of that body of work that's quoted and referenced there, but certainly it's not all of it.
Q. The second statement that says, the TVT-O

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arms pull unevenly, what is your support for that?
A. That's based just on my -- you know, my clinical experience, as well as taking care of patients with complications, and seeing contraction more on one side or the other that seems to cause undue amount of pain on that side. And also in patients that have extrusions and erosions in that area, it seems to have been in those instances pulling unevenly on that side.
Q. And I don't think I ever asked you. You have never implanted a TVT-O in a live patient, right?
A. I have not.
Q. The third sentence says, As this inevitable shrinkage occurs, the TVT-O mesh arms pull on the obturator and levator ani. Is that also based on your clinical experience?
A. That's based on my clinical experience, as well as multiple papers in the literature describing different pain syndromes in patients that have transobturator slings or transobturator approach to pelvic floor meshes, with arms going through same exact tract as the transobturator slings, and describing things like actually syndromes, mesh

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contraction syndromes that cause exactly this.
Q. So you use those -- because those women in those studies have a transobturator pain, and they have a transobturator sling, and they have leg pain, you are making a causal connection between the two?
MS. MARIGLIANO: Object to the form.
THE WITNESS: Well, this isn't just talking about leg pain as well. This is talking about pain contraction syndromes throughout the pelvic floor musculature and levator ani.
Q. (By Ms. Maimbourg) Right, but the connection you're making, I want to just understand your opinions, is these women have a transobturator sling that went inside-out, and they have pain, and therefore, you are connecting the two.
MS. MARIGLIANO: Object to the form.
Q. (By Ms. Maimbourg) Right?
A. I am connecting the two, yes.
Q. And then you say, this force on the pelvic sidewall muscles causes pain during routine daily life activities, like sexual intercourse or defecation. Is that -- what is that based on?
A. Again, it's based on my clinical experience of dealing with hundreds of patients with

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these types of complications, as well as multiple reports and papers in the literature describing the exact type of syndromes that -- that women with transobturator approach slings, meshes that suffer pain from are -- are under growing.
Q. Can you name one of those articles?
A. Yeah, Bruce Finer and Chris Maher talk specifically about the mesh contraction syndrome, sidewall to sidewall.
Q. Is that in your reliance materials?
A. I'm not sure it is.
Q. All right. I'll check it on the break. And then the next sentence, and this is the last one before we take a break, it says, When pressure is placed on the mesh during normal activities, it is transmitted to the attachments in the pelvic sidewall, which also deforms and pulls on the muscle at the attachment points, causing significant pain. Would that be that Maher and Fine -- Fine --
MS. MARIGLIANO: Finer.
Q. (By Ms. Maimbourg) Finer article, or is there your personal experience, or what is that based on?
A. Again, it's not only just my personal

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experience, it's not only the Maher, Finer, you know, published report, it's also Mickey Karram's paper on mesh complications, it's Sandip Vasavada from the Cleveland Clinic talking about mesh complications in patients they're seeing, it's Hillary Cholhan's paper, which I know that's referenced in here that talks about transobturator slings causing an increased amount of pain versus a retropubic approach, because of this banding periurethrally sidewall to sidewall muscles pulling on the muscles in women that ultimately suffer from that. That was majority of the findings that they had in patients as well.
MS. MAIMBOURG: All right, let's take a break.
(A recess was taken.)
Q. (By Ms. Maimbourg) So we're back on the record. Doctor, in your report, you have identified Abbrevo as a safer option to the TVT-O, right?
A. Yes.
Q. And why is that your opinion?
A. It's my opinion based on, again, clinical experience with smaller mesh tape slings, meaning a shorter amount of mesh, and dealing with the various

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type of different slings. So basically, my clinical background, as well as studies in the literature, as well as Ethicon's own internal documents, basically confirming that there's less risk of groin pain and issues with the sling that does not go all the way through the groin muscles.

Q. The studies in the literature, would those be studies that show what -- what particular studies in the literature? Are they all cited here in your report?

A. They should be. I mean, specifically, there's been several studies that have been comparative trials with Abbrevo versus TVT-O. And all showing various amounts of decreased risk of groin pain, both in short-term and some in the long-term. Specifically, the paper from Brown, and Shaw and Rardin showing the fact that you have 9 percent rate of groin pain with the TVT-O versus 1 percent in Abbrevo. And 25 percent of those patients that had groin pain in the TVT-O required a groin dissection. So I mean, you weigh those risk/benefits and clearly the TVT-O -- Abbrevo looks like that it's a much safer alternative.

Q. From your extensive review of the Ethicon

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documents provided to you, do you know when the product went into development?

A. The product initially was basically Professor de Leval --

Q. I'm looking for a date.

A. The first time that it was brought up was 2004.

Q. When was it cleared by the FDA?

A. I believe 2009.

Q. The date I have is July 1st, 2010?

A. Okay.

Q. Would you perhaps accept my representation?

A. Sure.

Q. Do you agree that Abbrevo could not have been implanted before it was cleared by FDA?

A. I do. I believe as well, though, that it could have been developed and approved a whole lot before 2009.

Q. Do you agree that -- understanding what you're saying, you're saying that Ethicon should have put it into development sooner, but would you agree that if one of these plaintiffs in a case in which you've been identified as a general expert was

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implanted before July 1 of 2010, that Abbrevo was not a safer option for her because the product was not cleared?

A. Correct.

Q. Since it's your opinion that Abbrevo is a safer option than TVT-O, I would assume that you have no criticism of its design; is that true?

A. I still am critical of passing needles through the groin. I still believe that a Mini sling that does not have to be passed -- anything passed through the groin, including needles, would be a safer alternative, as long as the clinical efficacy and the safety is there as well with that procedure. So I'm not sure if I would go as far as I don't have any criticisms of the design of the Abbrevo.

Q. Well, might you show up in a case criticizing Abbrevo, where a plaintiff is claiming injuries? I mean, would it go that far?

MS. MARIGLIANO: Object to the form. Go ahead.

THE WITNESS: At this point in time, no, I don't believe that would be the case.

Q. (By Ms. Maimbourg) Do you have any criticisms of the polypropylene mesh that is used in

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the Abbrevo?

MS. MARIGLIANO: Object to the form.

THE WITNESS: I believe any criticism that I have of the mesh of TVT-O would be the same criticisms that I would have of it for the Abbrevo. I believe that since it's not as long, that there's a potential for less contraction and less kind of stretching out and curling and roping of the sling, which would be a positive for Abbrevo.

Q. (By Ms. Maimbourg) So when you were implanting the AMS devices, before they were removed from the market, they are polypropylene mesh slings, right?

A. Correct.

Q. And you didn't have any safety concerns about implanting that polypropylene mesh, did you?

A. No.

Q. Do you know anything about the difference between the polypropylene in -- in that Sparc sling and the polypropylene in any of the Ethicon products?

A. No.

Q. Now, in terms of the Abbrevo being a safer option, I know you relied on certain company

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documents that you cite here. Is any one of them more important to you than another, as you sit here?
A. What pages are we on now, or was it included -- or where are we going through?
Q. Actually, I don't know. You know what, I'm going to withdraw that question. We don't have the time.
A. Okay.
Q. Let's look at page 22. You see on the bottom, you say -- last paragraph, you say, these studies all show?
A. Yes.
Q. That paragraph, or that first sentence, is that kind of like a good summary of your opinions? You can just read it to yourself.
MS. MARIGLIANO: I'm going to object to the form.
Q. (By Ms. Maimbourg) Well, only one of your opinions. In other words -- I'll ask a different question.
You're saying here that the studies you've quoted show that the original TVT-O device was defective in design as to its procedural steps, the length of the mesh, the location of the exit point of

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the needles, and the risk of injury to the obturator and location of the mesh, right?
A. Yes.
Q. These lead, in your opinion, to an increased risk of postoperative groin pain, which you have defined as within the first six to 12 weeks, right?
A. Postoperative time frame, yes.
Q. And then also adductor, obturator, and levator ani pain. And you say, This type of pain can lead to up-regulation of the nerves to these muscles and the remainder of the pelvic floor resulting in spasms, vaginal pain, pain with intercourse, and bladder and bowel dysfunction. What is the basis for your opinion on that regard?
A. Again, the same basis of my opinions that we talked about on the previous issues with the contraction of the mesh from sidewall to sidewall, creating banding, creating pain, creating contraction of the muscles, and ultimately, creating this sort of dysfunction as well. So it has to do with all of those studies that we've already talked about.
Q. On page 22, you state, Ethicon continued to sell, despite evidence that Abbrevo was safer.

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And my question to you is -- I guess I'll find that -- oh, it's on 23, bottom of the first paragraph. You see that sentence?
A. Yes.
Q. When you use the word, safer, I just want to make sure I understand what you mean by that. Do you mean less long-term pain or less postoperative pain, or both?
A. Both.
Q. And that would be with respect to the comparative studies you already talked about today, at least one of the bases for that, right?
A. Yes.
Q. So the next section is about the defects of the device itself, and you talk about the mesh being twice the width of the hole in the tissue that the needle and cannula create to pass the mesh through the obturator and adductor muscles, right?
A. Yes.
Q. And you say that this causes folding and deformation of the mesh?
A. Yes.
Q. Does it cause that folding and deformation of the mesh, in your opinion, throughout the length

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of the mesh?
A. It at least does upon it's entry into the muscles and through the muscles in the leg itself.
Q. Is that -- is it -- is that the only place? I didn't -- I can't remember what you said in the beginning, you said at least at that point.
A. Well, minimally, it does at that point, because it could ultimately lead to the mesh not lying flat under the urethra as well, but initially, minimally, yes, it's going to roll and curl upon itself from the point of entry into the muscle all the way through the leg.
Q. And you base this on the fact that you have implanted TVT slings, and you have implanted TVT-O slings in fresh cadaver specimens, right?
A. Yes.
Q. And how many cadaver specimens were involved in what you did?
A. Probably three or four.
Q. Where did you get the measurements?
A. Which measurements?
Q. The ones you quote, about the cannula and the hole in the tissue?
A. I believe these were internal documents

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from Ethicon.
Q. Would this same defect also be present in Abbrevo?
A. Yes, but again, not -- for a very much shorter distance, though.
Q. And when you were implanting Monarc, and you were a consultant for AMS, did you know those dimensions? In other words, did you know the size, the width of the mesh compared to the needle holes?
A. No, not the exact width -- or not the exact width of the needle, or they also had a dilating tip on their mesh as well, that was designed to kind of try to prevent some of that, to actually dilate the tract, so that the mesh would lie flatter.
Q. After you implant a sling, are you able to detect through your examination with your finger if the mesh is lying flat?
A. Under the urethra, yes.
Q. And I think you say later in this section that this deformation causes scarification and contraction. Would your support for that be the same articles you just told me about?
A. Yes, and looking at evidence of contraction and scarring and fibrosis.

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Q. On page 25, you talk about -- you call this sheath technology?
A. Yes.
Q. You know what I'm referring to when I say that?
A. Yes.
Q. And I think you say it's clinically relevant, right?
A. Yes.
Q. And it's clinically relevant to what, causing pain?
A. I think causing pain, causing urinary obstructive symptoms, creating immediate tension that one would not desire at the time of the procedure, that ultimately could lead to some of these different issues.
Q. And are you, by citing to Marty Weisberg's memo here, are you suggesting that Marty Weisberg has confirmed that this sheath technology issue is clinically relevant?
MS. MARIGLIANO: Object to the form.
THE WITNESS: I believe that that was -- actually came out of an e-mail from him, stating that it was clinically relevant, secondary to

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those reasons.
(Exhibit 20 was marked for identification.)
Q. (By Ms. Maimbourg) Doctor, I've marked as Exhibit 20, the Weisberg memo that you referred to in your report. Just take a quick look at it. So this memo, and I don't mean to interrupt you if you're not done, has to do with fraying. Is this what you're suggesting that this sheath technology does, it frays the mesh? That's what you said, right?
A. This is specifically talking about fraying itself. I don't know if it's talking about sheath technology. It's talking about stretching the tape and the amount of stretch that it requires to fray.
Q. Well, you say in your report, Dr. Marty Weisberg noted as well that tension exacerbates mesh fraying?
A. Right.
Q. And then Marty Weisberg also says that there is no reason to expect that the fraying of the mesh or the particles generated would create any safety risks?
A. Right, it's clinically relevant, as noted above, meaning that if the sheath was not pulling off

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correctly and stretching the tape and having increased friction as the tape -- as the sheath was trying to be pulled off the tape, that would cause it to stretch and cause it to fray. So that's the relation to it being clinically relevant.
Q. But Marty Weisberg is not saying it's clinically relevant?
MS. MARIGLIANO: Object to the form.
THE WITNESS: Marty Weisberg is saying that if you stretch the tape, it frays out.
Q. (By Ms. Maimbourg) But he's not saying it's clinically relevant, is he?
A. Correct.
MS. MARIGLIANO: What are you saying is "it," the fraying?
MS. MAIMBOURG: Right.
Q. (By Ms. Maimbourg) I mean, I asked you why you cited this, and I'm just exploring it. So let's move on. Can you cite any medical literature for why this sheath technology, which you say causes stretching, fraying, and roping, why it's clinically relevant?
A. Yes, and I think I do down here just a little bit, which was the Dietz paper that took a

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look at postoperative urinary obstructive type symptoms between the Sparc and TVT procedure. Again, the Sparc procedure has a tensioning suture throughout it. I believe there's another study by Moalli that looked at the different stretch properties of the different meshes. The TVT mesh is the one that stretches the most. It deforms the most, it elongates, and it stays elongated.

So if that's happening during that time frame, then it's going to cause increased obstructive type symptoms, which Dietz showed in his paper, as well if it's been shown before as well with the folding, the curling, and that sort of thing, and mesh being contracted like that, that it can lead to increased risk of extrusion, erosion, and those issues as well.

Q. Does the Dietz article talk about pain?

A. It does not.

Q. On page 26 of your report, at the bottom, you say, The blind passage of the trocars is unreasonably dangerous. Do you use those terms, unreasonably dangerous, in your every day practice?

A. I wouldn't say that I wouldn't use them, so yeah, there's times that I would use those words,

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yes.

Q. And you say, It presents the unnecessary risk of tissue damage, vascular damage, nerve damage, and internal trauma. What is the support for that statement?

A. Again, that statement is based on my clinical experience, my education, my training, my years of doing research on midurethral tape slings, and seeing and treating complications of patients with those types of complications.

Q. Your next statement says, The helical shape of the needle itself and the original technique described leads to a much higher risk of obturator nerve injury compared to an outside-in technique. And your support for that is what?

A. Again, all of the different articles in the literature that we've reviewed that we've taken a look at, that talk about increased risk of postoperative and long-term pain, as well as the different anatomic studies that were done that are quoted in my report as well, talking about the reproducibility of passing the TVT-O needle and various risks to the obturator nerve branches, even following the IFU guidelines, including one done by

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Piet Hinoul prior to him joining Gynecare.

Q. Is that the study we talked about earlier?

A. Yes.

Q. Are you talking about, in this sentence, injury upon implantation or later nerve injury due to fibrosis?

A. Both.

Q. So your next statement about the shape of the needle and passing it causes the user to exit much more lateral in the leg, you can't be basing that on your personal experience, because you haven't implanted in a patient, right?

MS. MARIGLIANO: Object to the form.

THE WITNESS: Not in a live patient, but in a fresh frozen cadaver specimen, I have in direct comparison to outside-in needles. So I do have experience passing these type of needles, and it was the reason why I decided never to perform a TVT-O in a live patient.

Q. (By Ms. Maimbourg) And when did you do those cadavers?

A. Back in the 2005/'6 time frame.

Q. What was the circumstance?

A. It was a cadaver lab at the AMS facility,

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training.

Q. So you were, as an AMS preceptor and consultant, comparing a competitor product to your own?

A. It wasn't my own product. And again, if you take a look at the products that I used throughout the year -- throughout the years, I didn't use the Sparc product. When they didn't have a retropubic sling, I used a retropubic TVT sling. So what I wanted to do, at any point in time in my career, is if there were new products out, I wanted to be able to utilize and take a look at them, and utilize my own judgment to see if this is something that I should be doing instead of an outside-in approach.

So it had nothing to do with -- with them saying, can you look at this and find negativities in it compared to our sling. It was for my own good to say, okay, what are the pluses and negatives of an alternative approach, because if you've got something better, then I'm going to use that.

Q. Was this just you, or was it a group of docs?

A. I'm not sure who was there. It wasn't a

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training session per se, so I think there may have been a few different physicians there, trying different products.

Q. Was it more an R&D?

A. I think there was some R&D folks there, yeah.

Q. And since it was held by AMS, certainly the purpose of it was not to talk about the virtues of TVT-O and the inside-out approach.

MS. MARIGLIANO: Object to the form.

Q. (By Ms. Maimbourg) Right?

A. I think that -- I wouldn't say that. I would say that I think AMS, as a company as well, wanted to look into all competitive products to see, are they missing something. This is the only company, Gynecare, that was going from the inside to the outside with the TVT-O.

I think they also wanted to know internally, is there advantages to this, and let's get our experts to take a look at it, and tell us whether it is or not. My personal reasons for wanting to do that was what I explained before.

Q. All right. And so were you one of those experts who were called in by AMS to decide if this

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was something they should look into? Is that what you're representing that meeting to be?

A. No. I think you have to understand during different cadaver lab sessions, whether it was for -- to have consultants there to look at their products, new products, whether there was a training going on. They also had access to other products and competitive products, and so you had the opportunity to take a look at these things.

Q. Okay. On page 27 and 28 of your report, you talk about mechanical cut and laser cut mesh?

A. Yes.

Q. In summary, both are bad, right? According to your report, both are bad?

A. Well, I mean, I think that with the laser cut, I think the thought was, we can make the mesh stiffer, we can help prevent the stretching and the immediate fraying, and the immediate kind of roping of the mesh. However, with the laser cut, it also showed that there was higher rates of extrusions in certain products that had that in. So I think they, you know, both had negative aspects to them.

Q. Well, you outlined for both, the negative aspects, right?

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A. Right. I mean, my personal preference would be to have mechanically cut mesh that is not going to stretch out during implantation or removal of the sheath. And a tensioning suture in that mesh helps prevent that. I don't even know -- the interesting thing is that it's -- until I was made aware of some of these things about laser cut versus mechanical cut, I was never informed of any of these changes that they had made through this in TVT, and that both were available, and we might have one version versus another version at our hospital.

Q. So it's your belief that TVT was offered both as mechanical and laser cut?

A. I believe it is.

Q. Do you know which is used in Abbrevo?

A. I do not.

Q. So when you decided that Abbrevo was a safer option to TVT-O, it didn't really matter to you whether the mesh was laser cut or mechanical cut?

A. I think it's a less of issue for Abbrevo for the reasons we've described before as well. It's a much smaller piece of mesh. It's much less apt to -- you don't have to pull that mesh through as much tissue. There's 85 percent less mesh, so you're

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going to get less issues with stretching, curling, and putting on tension immediately.

Q. Do you believe in medical innovation?

A. Yes, I do.

Q. That's why you do clinical trials probably, right?

A. Yes.

Q. In terms of your failure to warn opinions that begin on page 48, are all of the TVT-O training materials that you reference there on your reliance list?

A. I believe so, yes.

Q. You said here, I have also reviewed IFUs for many other medical products. Which ones?

A. Well, I mean, those would be products that I've utilized throughout the years, so all those AMS products we've talked about, other products that I've implanted.

Q. Are there any that you reviewed for purposes of becoming a consultant in this litigation?

A. No. Well, not for this one, but I've reviewed IFUs for the Bard litigation.

Q. So you became familiar with the Bard IFU as you worked as a consultant?

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A. Yes, unless I had implanted any of those products.
Q. Had you?
A. The Avaultas, no. Nor the sling.
Q. How about the Boston Scientific products, I think you had said you -- had you implanted an Obtryx?
A. No.
Q. So you became familiar with Boston Scientific's IFU for a sling through your work as a medical/legal consultant?
A. Yes.
Q. And you became familiar with the TVT-O IFU because of your work as a medical consultant -- medical/legal consultant?
A. Yes.
Q. On page 29 of your report, you say, Physicians must be able to reasonably rely upon product IFUs to make informed decisions. That's your belief and opinion, right?
A. Yes, I believe it's one of the things that -- that you need to make an informed decision, yes.
Q. Right, so you'll agree the IFU is not an

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exclusive source of information about medical devices for doctors who are going to implant them?
A. No, it's not exclusive device or -- but it's an important one.
Q. You meant exclusive source?
A. Yes, I'm sorry.
Q. Doctors, before they implant a medical device, they should read the pertinent medical literature, should they not?
A. Yes, they should.
Q. And they should achieve competency before they implant a device?
A. Yes.
Q. Doctors also have sources of information, such as product training offered by manufacturers, right?
A. Yes, if it's offered.
Q. And they can go to CMEs to learn about the area of medicine in which they practice, and most CMEs may touch on devices, right?
A. Yes.
Q. And certainly, doctors can rely on their own experience in learning about a medical device?
A. Yes.

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Q. Do you agree that a manufacturer does not need to tell a surgeon about the basics of sterile technique when doing surgery?
A. No, that would be inherent to their training.
Q. So we don't -- and Ethicon doesn't have to tell surgeons to wash their hands, because if they don't, it could cause a fatal infection, right?
A. Correct.
Q. And manufacturers don't have to tell surgeons that they need to consider the type of anesthesia that the patient has to have before surgery?
A. Correct.
Q. And a manufacturer doesn't have to tell a surgeon about the different risks of different surgical positions a patient could be put in?
A. No, I disagree with that one, because specifically if the position is critical for placement of that product or procedure that is going to make it safer or decrease risk of complications, then yes, they are -- they should be responsible for relaying that information to physicians.
Q. You state in your report that a physician

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must be warned of a frequent -- of the frequency, severity, duration, and potential permanence of adverse events by a manufacturer. That is your opinion, correct?
A. Yes.
Q. What is the basis for your opinion that a manufacturer should warn of frequency, severity, duration, and potential permanence?
A. I think it's the surgeon's right to have that information at their hands, to be able to offer treatments and be forthcoming and forthright to their own patients, so that the patients can understand the risks and complications of any procedure they may be undergoing. So if that information is available to a manufacturer, then certainly it needs to be relayed to the physician and patients.
Q. When you were a consultant for AMS, did you advocate that position to them?
A. Yes.
Q. And did they put frequency, severity, duration, and potential permanence into their IFU?
MS. MARIGLIANO: Object to the form.
THE WITNESS: I don't know about that. I know during any type of professional education

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training that I did for them, we certainly relayed all of that information to the physicians.

Q. (By Ms. Maimbourg) Right, so a manufacturer can pass on information in ways other than in the IFU, right?

A. Sure, but you weren't asking me initially whether it was just in the IFU. You said, should they give this information.

Q. Okay. My fault. So just so I'm clear you're not saying that the IFU, to be adequate, must include frequency, severity, duration, and potential permanence of adverse events?

A. I am saying, yes, it should be included in the IFU.

Q. All right. And my question to you, then, is, when you were at -- when you were assisting AMS as a consultant, are you aware of whether AMS ever included that type of this information in the IFUs for its sling products?

A. I'm not aware specifically. I don't recall the IFU details specifically.

Q. And since you've read all the literature in that big binder before you, what should those

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numbers in the IFU be today for, let's say, the TVT retropubic as to the frequency of anything you want to pick right now, any adverse event?

MS. MARIGLIANO: Object to the form.

THE WITNESS: I think that it needs to be basically consistent with what's in the literature, what's in -- within the Cochrane reviews, the meta analysis, their own internal studies, their own documents. They've got internal studies that haven't been published before.

So whatever information they have, they should produce that, risk of mesh extrusion for the retropubic TVT seems to be generally in the range of 1 to 2.5 percent. That should be listed. So any of that information that's there, it should be in there.

Q. (By Ms. Maimbourg) You would agree, though, that the literature is quite varied as to how -- strike that.

You would agree with me that if you were going to go look for the frequency of a particular adverse event in the medical literature, you would find a variety of numbers?

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A. Sure. So they probably should include a variety of numbers, from 1 percent to 30 percent.

Q. That's your opinion?

A. Yes.

Q. Is it your opinion that the Instructions For Use should include a statement about mesh degradation?

MS. MARIGLIANO: Object to the form.

MS. MAIMBOURG: Can you tell me how I can cure that objection?

MS. MARIGLIANO: You said how -- number one, I don't think he's offering any opinions about degradation.

MS. MAIMBOURG: Okay. If he's not, then that's swell.

Q. (By Ms. Maimbourg) Are you offering any opinions about degradation?

A. No.

Q. Are you offering any opinions about excessive and chronic foreign body reaction?

A. Where are we looking at right now, or are we?

Q. I'm just asking, in general, are you going to give expert opinions about polypropylene mesh used

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in TVT-O, causing excessive and chronic foreign body reaction?

A. Only in relation to any type of chronic inflammatory effects, scarring, that occurs that would ultimately create pain from nerve or muscle damage.

Q. Are you saying that should be in the IFU?

A. I think if they have evidence of a chronic inflammatory response, and not a transitory inflammatory response, then that should be included in the IFU, yes.

Q. And based on everything you've reviewed, did Ethicon have that evidence?

A. Yes.

Q. And is what -- the evidence they had, is it included in your report at page 30?

A. Yes. Or actually, probably, I think it's on the next page as well.

Q. So you're quoting testimony from Piet Hinoul and Charlotte Owens. Is there anything else that you're relying on for your opinion?

A. I think that if you get to like tab number 20, on page 33, it gets into more of some of the different studies that were both in their internal

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documents, as well as meetings with Klosterhalfen, who Professor Klosterhalfen was one of their consultants, but did a lot of publishing in the literature about chronic inflammatory reactions, mesh contraction, and subsequent issues with pain and nerve entrapment.

Q. On page 32, you talking about the 2015 Instructions For Use?

A. Yes.

Q. With respect to TVT-O, correct? And you say, all of these risks were known to Ethicon before 2015?

A. Uh-huh.

Q. Is that a yes?

A. I'm sorry, yes.

Q. Can you say that these risks were not known to doctors before 2015, can you say that?

MS. MARIGLIANO: Object to the form.

THE WITNESS: I can say that some of these risks were probably not known to some or many doctors.

Q. (By Ms. Maimbourg) Some doctors knew them all, right?

MS. MARIGLIANO: Object to the form.

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THE WITNESS: Yes.

Q. (By Ms. Maimbourg) You knew them all before they were put in the IFU, right?

A. Yes.

Q. Have you done any surveys of doctors, or do you have any kind of base of knowledge to know what doctors who are implanting slings know or don't know?

A. Only based upon my experience of training and professional education of hundreds of doctors at various levels, in talking with them, and figuring out what they know and don't know, but no formal surveys, no.

Q. Is the 2015 IFU for TVT-O adequate, in your opinion?

A. I think the only thing that I would add to this would be the fact that it talks about needing multiple surgeries to remove the mesh, but it doesn't talk about the fact that it could be impossible to remove all the mesh, and that should be noted.

Q. Anything else to make it adequate?

A. I would also say the mesh is a permanent implant, significant dissection may be -- as a continuation of the -- the line that says, the mesh

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is a permanent implant, and significant dissection may be required if the mesh needs to be removed. That could cause -- that this could cause, you know, permanent -- even more permanent, more pain, and more nerve damage that's permanent to the leg. In addition, saying that there's no guarantee that all the mesh can be removed, or any of the complications caused by the mesh would be reversed by some -- a major operation like that.

Q. Anything else?

A. I don't believe so.

Q. So in this section of the report, you have many things that -- and I don't have the time to actually go through every one of them, that Ethicon should have warned about. And I want to be clear, are you saying that warning should have come in the Instructions For Use?

A. Yes.

Q. And if a doctor had gone through Ethicon training, and had learned it in training, but it was not in the IFU, would you feel that Ethicon had met its duty to warn?

MS. MARIGLIANO: Object to the form.

THE WITNESS: No, because not all

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physicians went through training. And Gynecare didn't require that training to be done through them. So somehow those risks have to be put out to the physicians, whether it's in an IFU, whether they're there at professional education, whether they're risks or complications that are occurring that they're finding out about after launch, a letter to physicians to -- for notification. So somehow, that has to get out.

Q. (By Ms. Maimbourg) On some of these warnings, on page 32 and 33, so bottom of 32, top of 33, you're referring to the de Leval data. And you're saying that that data showed that it was, in some instances, chronic and severe. And the de Leval data that you had cited earlier was not long-term data, so I'm wondering, what was it that you were relying on for that opinion?

A. What page are we looking at?

Q. Bottom of 32, top of 33. You say, the de Leval data which showed it, leg pain?

A. Right.

Q. Was not rare, was not transient, was not limited to the leg, and was, in some instances, chronic and/or severe?

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A. I mean, it was shown later in his trial with Waltregny that it wasn't transient, it was severe in some cases. So I believe that's what I was referring to.
Q. And again, chronic means what to you?
A. Chronic means lasting longer than six months.
Q. When you were implanting the Monarc sling, what were the complications you were seeing in your patients?
MS. MARIGLIANO: Object to the form.
THE WITNESS: We saw complications of mesh extrusion, urinary obstruction, urinary urgency frequency, dyspareunia, or pain with intercourse. Luckily, I didn't have any of my own patients that suffered from groin pain, so that wasn't really an issue. So those were the major complications.
Q. (By Ms. Maimbourg) With respect to the Sparc sling that you're using now, what have been the complications that you're seeing in your own patients?
MS. MARIGLIANO: Object to the form.
THE WITNESS: The RetroArc.

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Q. (By Ms. Maimbourg) Did I say that wrong?
A. You said the Sparc. Sparc means top-down. RetroArc means the same sling from bottom-up.
Q. Then I apologize, and I meant the RetroArc?
A. The same.
Q. The same that you just listed?
A. Yes.
Q. Any groin pain?
A. No.
Q. Do you believe that the IFU for the RetroArc is adequate?
A. I haven't looked at it critically.
Q. Would you hold this same opinion as to all of the warnings that you say should have been in the Ethicon TVT-O IFU -- let me strike that, and ask a different question.
Putting the groin pain aside, you have a lot of opinions here about different things that should have been in the TVT-O IFU, would you agree with me?
A. Yes.
Q. Do you agree that those same warnings ought to be in the RetroArc IFU?

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A. Yes.
Q. They ought to be in every IFU for every sling, right?
A. Yes.
Q. On the inadequate physician training issue, on page 39, you -- it's a short section, but you talk about the e-mail from Marianne Kaminski?
A. Uh-huh.
Q. Right? Yes?
A. Yes.
Q. And so I guess to sum it up, this message is perhaps -- well, let me see what you say. The company intended to have sales representatives train physicians on the TVT-O procedure, right? That's what you say?
A. Yes.
Q. Do you know for a fact that sales reps trained doctors how to implant TVT-O?
A. Yes.
Q. Who is that?
A. I don't know specific -- I mean, I just know in discussions from reps that I've known that have -- that have utilized -- you know, worked in this field, discussions with them, discussions with a

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rep that used to work for Gynecare, that he did end up, you know, training physicians, yes.
Q. So I'm not interested in the sales reps for any other company, but I do want to know the name or names of any Gynecare rep that you are relying on for this statement?
A. Marquel Fleetwood.
Q. Mark?
A. Marquel.
Q. Is that M-A-R --
A. Q-U-E-L.
Q. And what's his last name?
A. Fleetwood.
Q. And he was a Gynecare rep?
A. He was.
Q. He was your rep?
A. Yeah, I believe he was for a period of time. He's worked with different companies, but he started with Gynecare, yes.
Q. And he told you, just so I'm clear when I interview him, you're saying under oath that he told you that he trained doctors how to implant TVT-Os himself?
A. Yes.

Q. How many times did he do it?
A. I don't know.
Q. And he -- you didn't misinterpret what he said, because he wasn't saying that he sent them to training, you're saying he trained them?
MS. MARIGLIANO: Object to the form.
THE WITNESS: I'm saying that he went to a physician's operating room who had never done a TVT-O before, and walked them through it, or a TVT procedure, yes.
Q. (By Ms. Maimbourg) Was it TVT or TVT-O?
A. I don't know which -- which it was.
Q. And you know the credentialing for procedures is done by hospitals, not by medical device manufacturers?
A. Correct.
Q. And that's across the board in the United States, right?
A. Yes.
Q. So that physician obviously was credentialed by his or her hospital to do that procedure?
A. He should have been, yes.
MS. MARIGLIANO: I think you have about

four or five minutes.
Q. (By Ms. Maimbourg) I think I'm just about at the end of my time, so I'm going to ask a general question. You know, obviously, this is a long report, and I had a limited amount of time. I tried to hit the big points.
A. Okay.
Q. I guess I'd like to ask you if there is any major opinion that I missed, or any major paper that you're going to rely on, or any particular document that I should spend my last four minutes on?
MS. MARIGLIANO: I'm just going to object to the form of that question.
THE WITNESS: I don't believe so.
Q. (By Ms. Maimbourg) Okay. Would you like to read the transcript, or would you like to waive your right to read the transcript?
A. Read it, please.
MS. MARIGLIANO: We'll read it.
MS. MAIMBOURG: Okay. So we're done.
MS. MARIGLIANO: This deposition is concluded.
(Deposition concluded at 1:00 p.m.)

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ERRATA
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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
ROBERT D. MOORE, D.O. DATE

Subscribed and sworn to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public

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Georgia CCR-B-2289

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STATE OF GEORGIA:
COUNTY OF CLAYTON:

I, F. Renee Finkley, a Certified Court Reporter in and for the State of Georgia, do hereby Certify:

That prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify to the truth, the whole truth, and nothing but the truth.

That said deposition was taken before me at the time and place set forth and was taken down by me in shorthand and thereafter reduced to computerized transcription under my direction and supervision, and I hereby certify the foregoing deposition is a full, true and correct transcript of my shorthand notes so taken.

I further certify that I am not of kin or counsel to the parties in the case, and I am not in the regular employ of counsel for any of the said parties, nor am I in any way financially interested in the result of said case.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 15th day of April, 2016.

_____ ____
F. Renee Finkley, RPR, RMR, CRR, CLR
Georgia CCR-B-2289